CENTER FOR DEVICE REGULATION, RADIATION HEALTH AND RESEARCH (CDRRHR)
EXTERNAL SERVICES

1.AMENDMENT APPLICATION OF SALES PROMO PERMIT

The application for the amendment in the permit for the conduct of sales promotion schemes for medical devices.

Center/Office/Division	:	Center for Device Regulation, Radiation Health and Research – Licensing and Registration Division
Classification	:	Complex
Type of Transaction	:	G2B - Government-to-Businesses
Who May Avail	:	Medical Device Manufacturers/Distributors (Importer/Exporter/Wholesaler)/Trader
Fees to be Paid	:	Php300.00 + Php10.00 LRF per certification

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
Letter of Intent specifying the type of amendment	Applicant
Copy of previously issued valid promo permit	Applicant
Supporting documents for the requested amendment	Applicant
Proof of payment	FDA Cashier
Self-Assessment Form	Applicant
Accomplished Integrated Application Form	Applicant
List of participating products in Excel Format.	Applicant
Submission schedule is as follows: For companies with names beginning with numbers 0-9 and letters A-M: Every Thursday from 8:00 AM to 5:00 PM. For companies with names beginning with letters N-Z: Every Friday from 8:00 AM to 5:00 PM. This schedule applies to working days only and excludes national and declared non-working days. In the event of a holiday/non-working day, then the regular schedule shall be followed on the next working and scheduled submission day.	

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME*	PERSON RESPONSIBLE
1. Client sends an email containing the PDF of their application to fdac.letters@fda.gov.ph following the correct schedule.	1. Receiving officer generates a Document Tracking Number (DTN) and sends an acknowledgment email / order of payment to the client	None	Timeline starts after posting of payment	FDAC Officer
2. The applicant company receives the Order of Payment and pays the assessed fee through FDAC Cashier or any other means prescribed by FDA. (e.g. BANCNET, LANDBANK ONCOLL). The Order of Payment will only be valid for 24 hours.	2. FDA receives the payment from the applicant company for posting.	PHP310.00		FDA Cashier
3. The applicant company receives the official receipt and sends the proof of payment to FDA Action Center (FDAC) through email	3.1 FDAC forwards the application to CDRRHR.	None		FDAC Officer
	3.2 The CDRRHR assigns the application to the evaluator.	None	1 working day	CDRRHR Administrative Staff

	3.3 The technical evaluator reviews the application. Recommends approval/ disapproval.	None	2 working days	Technical Evaluator
.	3.4 Quality Assurance - Checking of recommendation of the Supervisor	None	1 working day	LRD Chief
	3.5 Final Approval/Disapproval and signature of the Director.	None	1 working day	CDRRHR Director
.	3.6 Assigning of number and printing of permit. Scanning and transmitting permit to the Records Section.	None	1 working day	CDRRHR Administrative Staff
4. Pick-up of Certificate	4.Queuing and endorsement to the FDA Releasing Section.	None	1 working day	AFS Records Officer / Administrative Officer
	TOTAL	PHP 310.00 per certification	7 working days	

*Day 1 commences upon the receipt of the proof of payment / posting of payment.

2.APPLICATION FOR VARIATION OF CERTIFICATE OF PRODUCT REGISTRATION (CPR) OF IN-VITRO DIAGNOSTIC DEVICES/REAGENTS (IVD) AND CERTIFICATE OF MEDICAL DEVICE REGISTRATION (CMDR)

The application for minor or major variations or amendments in the CPR of medical devices and in-vitro diagnostic devices or reagents.

Center/Office/Division	:	CDRRHR-LRD
Classification	:	Highly Technical
Type of Transaction	:	G2B - Government-to-Businesses
Who May Avail	:	Medical Device Manufacturers/Distributors (Importer/Exporter/Wholesaler)/Trader
Fees to be Paid	:	Php500.00 + Php10.00 = Php510.00 Other fees: Extension of shelf life: Php1,000.00 + Php10.00 = Php1,010.00 Change in brand name: Php2,500.00 + Php25.00 = Php2,525.00

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
Change of Business Name and Address of Manufacturer/Trader/Importer/ Distributor	
1. Letter of request - Should indicate the current and proposed changes - Should include in the letter if there is a renewal application and indicate document tracking Number	Applicant
2.Valid License to Operate (LTO) reflecting the new business name and address of manufacturer/trader/importer/distributor with the source reflected in the LTO	Applicant

3. Original Certificate of Product Registration (CPR) - Should submit back and front sides	Applicant
4. Complete labeling requirements (Primary, Secondary, and Inserts) - Submit current and proposed labels	Applicant
Change in Ownership (Inclusion/Deletion or Change in Trader/Importer/Distributor)	
Letter of request Should indicate the current and proposed changes Should include in the letter if there is a renewal application and indicate document tracking number	Applicant
2. Valid LTO reflecting the source	Applicant
3. Termination of Contract/Deed of Assignment	Applicant or Principal/Source/ Manufacturer
4. Agreement with the new company must be valid	Applicant or Principal/Source/ Manufacturer
5. Original CPR - Should submit back and front sides	Applicant
6. Complete labeling requirements (Primary, Secondary, and Inserts) - Submit current and proposed labels	Applicant

Request for Change of Shelf Life	Where to secure
Letter of request Should indicate the current and proposed changes Should include in the letter if there is a renewal application and indicate document tracking number	Applicant

2. Previously submitted stability data	Principal/Source/ Manufacturer
3. Real time data supporting the change of shelf life - Must be signed by the person who performed the analysis	Principal/Source/ Manufacturer
4. Copy of CPR - Should submit back and front sides	Applicant
5. Complete labeling requirements - Submit current and proposed labels	Applicant or Principal/Source/ Manufacturer
Change of Manufacturing Site (Same Subsidiary) With No Change in The Formulation, Equipment, and Manufacturing Procedure	Where to Secure
Letter of request Should indicate the current and proposed changes Should include in the letter if there is a renewal application and indicate document tracking number	Applicant
. Submit justification or supporting documents to show that the proposed manufacturer is a subsidiary of the current or approved manufacturer	
Letter from the manufacturer stating that there is no change in the formulation, equipment and manufacturing procedure	Principal/Source/ Manufacturer
4. Valid LTO	Applicant
5. Copy of submitted Notification of Source - The list of sources should reflect the proposed manufacturing site	Applicant
6. Formulation (for solutions) or List of Raw Materials (with the corresponding amount of raw materials used, if applicable) issued by the current and proposed manufacturer	Principal/Source/ Manufacturer
7. Manufacturing flowchart (current and proposed) Include brief narrative description of the manufacturing flowchart	Principal/Source/ Manufacturer
8. Finished product specification (current and proposed)	Principal/Source/ Manufacturer

9. For Imported Products – authenticated or apostilled GMP/ISO Certificate reflecting the new manufacturing site The GMP/ISO certificate should be valid	Principal/Source/ Manufacturer
10. Sterilization process and latest result of sterilization validation conducted/issued by the new manufacturing site	Principal/Source/ Manufacturer
11. Valid ISO Certificate of the sterilizing company (if there is a change in sterilization company)	Principal/Source/ Manufacturer
12. Copy of CPR - Should include back and front sides	Applicant
13. Complete labeling requirements (Primary, Secondary, and Inserts) - Submit current and proposed labels	Applicant or Principal/Source/ Manufacturer
Change of Brand Name (From Generic to Brand, Change of Brand to Another, Deletion of Brand)	Where to Secure
Letter of request Should indicate the current and proposed changes Should include in the letter if there is a renewal application and indicate document tracking number	Applicant
Copy of CPR - Should include back and front sides	Applicant
Certificate from IPO for local brand name. For imported products, the manufacturer's declaration that allows the use of the brand name.	Applicant
Official letter from the product owner regarding the change of brand name and declaration that there is no other change to the product/label except for the brand name	Principal/Source/ Manufacturer
Complete labeling requirements (Primary, Secondary, and Inserts) - Submit current and proposed labels	Applicant or Principal/Source/ Manufacturer

Change of Storage Condition	Where to Secure

Letter of request Should indicate the current and proposed changes Should include in the letter if there is a renewal application and indicate document tracking number	Applicant

Change/Additional Indications	Where to Secure
Letter of request Should indicate the current and proposed changes Should include in the letter if there is a renewal application and indicate document tracking number	Applicant
Copy of CPR Submit front and back sides	Applicant
Approval letter issued by a government agency or notified body	Principal/Source/ Manufacturer
Studies to support the additional indication	Principal/Source/ Manufacturer
Complete labeling requirements (Primary, Secondary, and Inserts) - Submit current and proposed labels	Principal/Source/ Manufacturer

Change of Re-Packer/Packer	Where to Secure
Letter of request Should indicate the current and proposed changes Should include in the letter if there is a renewal application and indicate document tracking number	Applicant

2. Termination of contract with the previous re-packer/packer	Applicant or Principal/Source/ Manufacturer
3. Agreement of with the new re-packer/packer	Applicant or Principal/Source/ Manufacturer
4. Copy of CPR - Submit front and back sides	Applicant
5. Complete labeling requirements (Primary, Secondary, and Inserts) - Submit current and proposed labels	Principal/Source/ Manufacturer

Change of Label Design	Where to Secure
Letter of request Should indicate the reason for change Should indicate the current and proposed changes Should include in the letter if there is a renewal application and indicate document tracking number	Applicant
2. Copy of CPR - Submit front and back sides	Applicant
3. Currently approved label design	Applicant
4. Proposed label with the new design	Applicant or Principal/Source/ Manufacturer
Change of Packaging	Where to Secure
Letter of request Should indicate the reason for change Should indicate the current and proposed changes Should include in the letter if there is a renewal application and indicate document tracking number	Applicant

Copy of CPR - Submit front and back sides	Applicant
3. Appropriate scientific data on new packaging	Principal/Source/ Manufacturer
4. Proof that no interaction between the product and packaging material occur	Principal/Source/ Manufacturer
5. Comparative tabulated format of specifications of currently approved and proposed packaging material	Applicant or Principal/Source/ Manufacturer
Additional Presentation [e.g. (1) Registered box x 100's, additional presentation of 1 box x 500's; (2) registered 60mL, additional of 120mL]	Where to Secure
Letter of request Should indicate the current and proposed changes Should include in the letter if there is a renewal application and indicate document tracking number	Applicant
2. Copy of CPR - Submit front and back sides	Applicant
3. Currently approved and proposed presentation	Applicant
Re-classification (from other classification to Medical Device)	Where to Secure
1. Letter of request	Applicant
2. Letter from the other Center regarding re-classification of the product (if applicable)	Applicant
3. Original CPR issued by another Center	Applicant
4. Complete requirements for initial registration	Applicant
Addition of Codes/Reference Number/Article Number	Where to Secure
Letter of request Should indicate the current and proposed changes Should include in the letter if there is a renewal application and indicate document tracking number	Applicant

2. Copy of CPR - Submit front and back sides	Applicant
3. Declaration from the manufacturer that there is no change in the manufacturing process, sterilization process and raw materials	Principal/Source/ Manufacturer
4. Provide previous list of raw materials and manufacturing flowchart of the previously approved codes	Principal/Source/ Manufacturer
5. List of raw materials and manufacturing flowchart for the proposed code/s	Principal/Source/ Manufacturer
6. Complete tabulated format of the finished product specification of the currently approved codes and proposed codes	Principal/Source/ Manufacturer
7. Colored photos of the current and proposed codes	Applicant or Principal/Source/ Manufacturer
8. Labels of the current and proposed codes	Applicant or Principal/Source/ Manufacturer
Deletion of Codes/Reference Number/Article Number	Where to Secure
Letter of request Indicate the reason for deletion Should indicate the current and proposed changes Should include in the letter if there is a renewal application and indicate document tracking number	Applicant
Official letter from the product owner regarding the deletion	Principal/Source/ Manufacturer
3. Copy of CPR - Submit front and back sides	Applicant

Additional Sterilization Site	Where to Secure

Letter of request Should indicate the current and proposed changes Should include in the letter if there is a renewal application and indicate document tracking number	Applicant
2. Copy of CPR - Submit front and back sides	Applicant
3. Sterilization procedure and revalidation protocol issued by the currently approved sterilizing company.	Principal/Source/ Manufacturer
4. Sterilization procedure and revalidation protocol issued by the proposed sterilizing company.	Principal/Source/ Manufacturer
5. Latest result of sterilization revalidation of the new sterilizing company	Principal/Source/ Manufacturer
6. ISO Certificate of the new sterilizing company	Principal/Source/ Manufacturer

Change in Instructions for Use	Where to Secure
Letter of request Should indicate the current and proposed changes Should include in the letter if there is a renewal application and indicate document tracking number	Applicant
2. Copy of CPR - Submit front and back sides	Applicant
3. Previously approved instructions for use	Applicant or Principal/Source/ Manufacturer
4. Proposed instructions for use	Principal/Source/ Manufacturer

5. For technical changes, submit study to support the change in instructions for use	Principal/Source/ Manufacturer

Change/Addition of Source of Raw Materials	Where to Secure
Letter of request Indicate the reason for the change/addition of source of raw materials Should indicate the current and proposed changes Should include in the letter if there is a renewal application and indicate document tracking number	Applicant
2. Copy of CPR - Submit front and back sides	Applicant
3. Comparative tabulated format of the analysis of raw materials of the currently approved and new source	Applicant or Principal/Source/ Manufacturer
4. Comparative tabulated format of finished product specification of the currently approved and new source	Applicant or Principal/Source/ Manufacturer

Change of Test Procedure	Where to Secure
Letter of request Indicate the reason for the change of test procedure Should indicate the current and proposed changes Should include in the letter if there is a renewal application and indicate document tracking number	Applicant
2. Copy of CPR - Submit front and back sides	Applicant
3. Description of the analytical methodology, a summary of validation data and comparative analytical results between the currently approved and proposed test	Principal/Source/ Manufacturer

Submission schedule is as follows: > For companies with names beginning with numbers 0-9 and letters A-M: Every Thursday from 8:00 AM to 5:00 PM. > For companies with names beginning with letters N-Z: Every Friday from 8:00 AM to 5:00 PM. This schedule applies to working days only and excludes national and declared non-working days. In the event of a holiday/non-working day, then the regular schedule shall be followed on the next working and scheduled submission day.	

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME*	PERSON RESPONSIBLE
Client sends an email containing the PDF of their application to fdac.letters@fda.gov.ph following the correct schedule and pays the corresponding fee.	1. Receiving officer generates a Document Tracking Number (DTN) and send and acknowledgment email / order of payment to the client.			FDAC Officer
The applicant company receives the Order of Payment and pays the fee through the FDAC Cashier or through the other means prescribed by the FDA. The Order of Payment is only valid for 24 hours after issuance.	2. FDA receives the payment from the applicant company.	*Fees depend on the total amendment request of the client.	Timeline starts after posting of payment	FDA Cashier
The applicant company receives the official receipt and sends the proof of payment to the FDAC through email.	3.1 FDAC forwards the application to the CDRRHR.		1 working day	FDAC Officer

	3.2 Decking of the application to the evaluator.			CDRRHR Administrative Staff
	3.3 The technical evaluator reviews the application and recommends approval/disapproval.		11 working days**	CDRRHR Technical Evaluator
	3.4 Quality Assurance – checking and recommendation of the Supervisor.		3 working days	CDRRHR LRD Division Chief
	3.5 Preparation of Letter of Approval or Disapproval of Variation		1 working day	CDRRHR Technical Evaluator
	3.6 Final approval and disapproval and signature of the Center Director.		1 working day	CDRRHR Director
	3.7 Scanning of the approval letter. Transmitting of the approval letter to the Records Section. Queuing and endorsement to the FDA Releasing Section.		3 working days	Administrative Officer
	TOTAL	Php510.00/ Php1,010.00/ Php2,525.00	20 working days***	

*Day 1 commences upon the receipt of the proof of payment / posting of payment.

**Timeline provided is for applications that are complete and correct with no Notice of Deficiencies issued.

***Service is covered under Republic Act No. 3720 Section 21 as amended by Executive Order No. 175 Section 13.

3.RE-APPLICATION FOR CMDR AND IVDR INITIAL APPLICATIONS

The client's response or compliance to the issued Letter of Disapproval following their initial registration application. Clients are given 60 calendar days to comply from the date of the LoD issuance.

Center/Office/Division	:	CDRRHR-LRD
Classification	:	Highly Technical
Type of Transaction	:	G2B - Government-to-Businesses
Who May Avail	:	Medical Device Manufacturers/Distributors (Importer/Exporter/Wholesaler)/Trader
Fees to be Paid	:	Php 1,000.00 + 1% LRF = Php1,010.00

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
Letter of Intent	Applicant.
Copy of the Letter of Disapproval/Reapplication.	Applicant
Compliance Documents	Applicant/Principal/ Manufacturer
Payment	FDA Cashier
NOTES: Submit an electronic/scanned copy (in PDF searchable format of at least 150 dpi) The soft copy should be arranged according to the checklist of requirements. The file name should consist of the name of the requirement. The electronic copy should be contained either in one single continuous file per requirement or single continuous file for all requirements.	

Submission schedule applies to working days only and excludes national and declared non-working days. In the event of a holiday/non-working day, then the regular schedule shall be followed on the next working and scheduled submission day.	

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
Client sends an email containing the PDF of their compliance to fdac.pacd@fda.gov.ph within the prescribed time period stipulated in the Letter of Disapproval/Reapplication.*	1.1 Receiving officer sends an acknowledgment email to the client and assigns a new DTN to the application. FDAC forwards the re-application file to CDRRHR.	Php1,010	1 working day	FDAC Officer
	1.2 CDRRHR receives the re-application file and decks to the evaluator	None	1 working day	CDRRHR Administrative Staff
	1.3 Technical evaluation of application. Recommendation of Approval or Final Disapproval	None	10 working days	CDRRHR Technical Evaluator
	1.4 Quality Assurance - Checking of	None	4 working days	CDRRHR LRD Division Chief

	recommendation of the Supervisor			
	1.5 Drafting and finalization of certificate/disapproval letter	None	1 working day	CDRRHR Technical Evaluator
	1.6 Final Approval/Disapproval and signature of the Director	None	1 working day	CDRRHR Director
	1.7 Scanning and transmittal of certificate/disapproval letter to the FDA Records Section	None	1 working day	CDRRHR Administrative Staff
	1.8 Queuing and endorsement to the FDA Releasing Section.	None	1 working day	AFS Records Officer / Administrative Officer
	TOTAL	P1,010.00	20 working days**	

*Submission period is within sixty (60) days from the issuance date of the Letter of Disapproval/Re-application.

**Service is covered under Republic Act No. 3720 Section 21 as amended by Executive Order No. 175 Section 13.

4.RE-APPLICATION FOR RENEWAL OF CMDR/CPR and IVDR

The client's response or compliance to the issued Letter of Disapproval following their renewal application. Clients are given 30 calendar days to comply from the date of the LoD issuance.

Center/Office/Division	:	CDRRHR-LRD
Classification	:	Highly Technical
Type of Transaction	:	G2B - Government-to-Businesses
Who May Avail	:	Medical Device Manufacturers/Distributors (Importer/Exporter/Wholesaler)/Trader
Fees to be Paid	:	Php 1,000.00 + 1% LRF = Php1,010.00

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
Letter of Intent	Applicant
Copy of the Notice of Deficiencies	Applicant
Compliance Documents	Applicant / Principal/Manufacturer
Payment	FDA Cashier

NOTES: Submit an electronic/scanned copy (in PDF searchable format of at least 150 dpi) The soft copy should be arranged according to the checklist of requirements. The file name should consist of the name of the requirement. The electronic copy should be contained either in one single continuous file per requirement or single continuous file for all requirements. Submission schedule applies to working days only and excludes national and declared non-working days. In the event of a holiday/non-working day, then the regular schedule shall be followed on the next working and scheduled submission day.	

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
Client sends an email containing the PDF of their compliance to fdac.pacd@fda.gov.ph within the prescribed time period stipulated in the notice of deficiency.*	1.1 Receiving officer sends an acknowledgment email to the client and assigns a new DTN to the application. FDAC forwards the re-application file to CDRRHR.	Php1,010.00	1 working day	FDAC Officer
	1.2 CDRRHR receives the re-application file and decks to the evaluator	None	1 working day	CDRRHR Administrative Staff
	1.3 Technical evaluation of application. Recommendation of Approval or Final Disapproval	None	10 working days	CDRRHR Technical Evaluator
	1.4 Quality Assurance - Checking of recommendation of the Supervisor	None	4 working days	CDRRHR LRD Division Chief

	1.5 Drafting and finalization of certificate or disapproval letter	None	1 working day	CDRRHR Technical Evaluator
	1.6 Final Approval/Disapproval and signature of the Director	None	1 working day	CDRRHR Director
	1.7 Scanning and Transmittal of certificate or disapproval letter to the FDA Records Section.	None	1 working day	CDRRHR Administrative Staff
	1.8 Queuing and endorsement to the Releasing Section	None	1 working day	AFS Records Officer / Administrative Officer
	TOTAL	Php1,010.00	20 working days**	

*Submission period is within thirty (30) days from the issuance date of the Letter of Disapproval/Re-application.

**Service is covered under Republic Act No. 3720 Section 21 as amended by Executive Order No. 175 Section 13.

5.COMPLIANCE FOR CMDR AND IVDR APPLICATIONS

The client's response or compliance to the issued Notice of Deficiencies following their initial registration application. Clients are given 90 calendar days to comply from the date of the NOD issuance.

Center/Office/Division	:	CDRRHR-LRD
Classification	:	Highly Technical
Type of Transaction	:	**G2B - Government-to-Businesses**
Who May Avail	:	Medical Device Manufacturers/Distributors (Importer/Exporter/Wholesaler)/Trader
Fees to be Paid	:	None

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
1. Letter of Intent	Applicant.
2. Copy of the Notice of Deficiency	Applicant
3. Compliance Documents	Applicant / Principal/Manufacturer

NOTES: • Submit an electronic/scanned copy (in PDF searchable format of at least 150 dpi) • The soft copy should be arranged according to the checklist of requirements. The file name should consist of the name of the requirement. The electronic copy should be contained either in one single continuous file per requirement or single continuous file for all requirements. Submission schedule applies to working days only and excludes national and declared non-working days. In the event of a holiday/non-working day, then the regular schedule shall be followed on the next working and scheduled submission day.	

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
1. Client sends an email containing the PDF of their compliance to fdac.pacd@fda.gov.ph within the prescribed time period stipulated in the Notice of Deficiencies.*	1.1 Receiving officer sends an acknowledgment email to the client. FDAC forwards the compliance to CDRRHR.	None	1 working day	FDAC Officer
	1.2 CDRRHR receives the compliance and decks the file to the evaluator.	None	1 working day	CDRRHR Administrative Staff
	1.3 Technical evaluation of application. Recommendation of re-application or proceed to Approval.	None	10 working days	Technical Evaluator
	1.4 Quality Assurance - Checking of recommendation of the Supervisor	None	4 working days	LRD Chief
	1.5 Final Approval/Disapproval and signature of the Director	None	2 working days	CDRRHR Director

	1.6 Scanning and Transmittal of Re-application letter to Records Section	None	1 working day	CDRRHR Administrative Staff
	1.7 Queuing and Endorsement to Releasing Section	None	1 working day	AFS Records Officer / Administrative Officer
	TOTAL		20 working days**	

**Submission period is within ninety (90) days from the issuance date of the Notice of Deficiencies (NOD).*

**Service is covered under Republic Act No. 3720 Section 21 as amended by Executive Order No. 175 Section 13.

6.COMPLIANCE FOR RENEWAL OF CMDR/CPR AND IVDR

The client's response or compliance to the issued Notice of Deficiencies following their renewal application. Clients are given 30 calendar days to comply from the date of the NOD issuance.

Center/Office/Division	:	CDRRHR-LRD
Classification	:	Highly Technical
Type of Transaction	:	**G2B - Government-to-Businesses**
Who May Avail	:	Medical Device Manufacturers/Distributors (Importer/Exporter/Wholesaler)/Trader
Fees to be Paid	:	None

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
1. Letter of Intent	Applicant
2. Copy of the Notice of Deficiencies.	Applicant

3. Compliance Documents	Applicant / Principal/Manufacturer
NOTES: • Submit an electronic/scanned copy (in PDF searchable format of at least 150 dpi) • The soft copy should be arranged according to the checklist of requirements. The file name should consist of the name of the requirement. The electronic copy should be contained either in one single continuous file per requirement or single continuous file for all requirements. Submission schedule applies to working days only and excludes national and declared non-working days. In the event of a holiday/non-working day, then the regular schedule shall be followed on the next working and scheduled submission day.	

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
1. Client sends an email containing the PDF of their compliance to fdac.pacd@fda.gov.ph within the prescribed time period stipulated in the Notice of deficiencies.*	1.1 Receiving officer sends an acknowledgment email to the client. FDAC forwards the compliance document to CDRRHR.	None	1 working day	FDAC Officer
	1.2 CDRRHR receives the compliance and decks to the evaluator	None	1 working day	CDRRHR Admin Staff
	1.3 Technical evaluation of application and recommendation for approval or disapproval.	None	10 working days	Technical Evaluator
	1.4 Quality Assurance - Checking of recommendation of the Supervisor	None	4 working days	LRD Chief
	1.5 Final Approval/Disapproval and signature of the Director	None	2 working days	CDRRHR Director

	1.6 Scanning and transmittal of the certificate/disapproval letter to the Records Section.	None	1 working day	CDRRHR Administrative Staff
	1.7 Queuing and endorsement to the FDA Releasing Section	None	1 working day	AFS Records Officer / Administrative Officer
	TOTAL		**20 working days****	

**Submission period is within thirty (30) days from the issuance date of the Letter of Disapproval/Re-application.*

**Service is covered under Republic Act No. 3720 Section 21 as amended by Executive Order No. 175 Section 13.

7.COMPLIANCE FOR VARIATION APPLICATIONS

The client's response or compliance to the issued Notice of Deficiencies following their CPR variation application. Clients are given 30 calendar days to comply from the date of the NOD issuance.

Center/Office/Division	:	CDRRHR-LRD
Classification	:	Highly Technical
Type of Transaction	:	G2B - Government-to-Businesses
Who May Avail	:	Medical Device Manufacturers/Distributors (Importer/Exporter/Wholesaler)/Trader
Fees to be Paid	:	None

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
Letter of Intent	Applicant

Copy of the Notice of Deficiencies	Applicant
Compliance Documents	Applicant / Principal/Manufacturer
NOTES: Submit an electronic/scanned copy (in PDF searchable format of at least 150 dpi) The soft copy should be arranged according to the checklist of requirements. The file name should consist of the name of the requirement. The electronic copy should be contained either in one single continuous file per requirement or single continuous file for all requirements. Submission schedule applies to working days only and excludes national and declared non-working days. In the event of a holiday/non-working day, then the regular schedule shall be followed on the next working and scheduled submission day.	

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
Client sends an email containing the PDF of their compliance to fdac.pacd@fda.gov.ph within the prescribed time period stipulated in the notice of deficiencies. *	1 Receiving officer sends an acknowledgment email to the client. FDAC forwards the compliance file to CDRRHR.	None	1 working day	FDAC Officer
	1.2 CDRRHR receives the compliance file and decks the file to the evaluator.	None	1 working day	CDRRHR Administrative Staff
	1.3 Technical evaluation of application. Recommendation for approval or disapproval.	None	10 working days	CDRRHR Technical Evaluator
	1.4 Quality Assurance - Checking of recommendation of the Supervisor.	None	4 working days	CDRRHR LRD Division Chief

	1.5 Final Approval/Disapproval and signature of the Director.	None	2 working days	CDRRHR Director
	1.6 Scanning and Transmittal of certificate or disapproval letter to the FDA Records Section.	None	1 working day	CDRRHR Administrative Staff
	1.7 Queuing and Endorsement to the FDA Releasing Section.	None	1 working day	AFS Records Officer / Administrative Officer
	TOTAL		20 working days**	

*Submission period is within thirty (30) days from the issuance date of the Notice of Deficiencies.

**Service is covered under Republic Act No. 3720 Section 21 as amended by Executive Order No. 175 Section 13.

8.ISSUANCE OF CERTIFICATE OF FREE SALES (CFS)

The application for certification that the medical device is registered and currently sold in the Philippines.

Center/Office/Division	:	CDRRHR-LRD
Classification	:	Complex
Type of Transaction	:	G2B - Government-to-Businesses
Who May Avail	:	Medical Device Manufacturers/Distributors (Importer/Exporter/Wholesaler)/Trader
Fees to be Paid	:	Php500.00 + Php10.00 LRF per product

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
1 Letter of Intent regarding application for Certificate of Free Sale List of all devices must be enumerated in one letter only. If the application is more than one CMDR/CMDN or if the product contains codes. The client must submit a Word Copy of the Letter of Intent.	Applicant
1 copy of Certificate of Medical Device Registration (CMDR) or Certificate of Medical Device Notification (CMDN). The CPR must be valid. For CMDR's/CMDN's currently undergoing the Amendment/Variation process, a letter of approval must be secured by the company prior to CFS application.	Applicant
License to Operate as Medical Device Manufacturer/ Exporter. Must be valid For cases that the company is not the Manufacturer or Trader, they must apply for additional activity as an Exporter For LTO currently undergoing the renewal process, submit proof of application for LTO renewal, including Official Receipt.	Applicant
Fee Computation of fee is per CPR as indicated in the letter of intent.	Applicant

5. If the Manufacturer/Trader is different from the Exporter, submit a copy of the agreement/authorization allowing them to export the medical device.	Applicant or Principal/Source/ Manufacturer
Submission schedule is as follows: For companies with names beginning with numbers 0-9 and letters A-M: Every Thursday from 8:00 AM to 5:00 PM. For companies with names beginning with letters N-Z: Every Friday from 8:00 AM to 5:00 PM. This schedule applies to working days only and excludes national and declared non-working days. In the event of a holiday/non-working day, then the regular schedule shall be followed on the next working and scheduled submission day.	

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME*	PERSON RESPONSIBLE
1. Client sends an email containing the PDF of their application to fdac.letters@fda.gov.ph following the correct schedule.	1. Receiving officer generates a Document Tracking Number (DTN) and sends an acknowledgment email / order of payment to the client	None	Timeline starts after posting of payment	FDAC Officer
2. The applicant company receives the Order of Payment and pays the assessed fee through FDAC Cashier or any other means prescribed by FDA. (e.g. BANCNET, LANDBANK ONCOLL). The Order of Payment will only be valid for 24 hours.	2. FDA receives the payment from the applicant company for posting	PHP510.00		FDA Cashier
3. The applicant company receives the official receipt and sends the proof of	3.1 FDAC forwards the application to CDRRHR.	None		FDAC Officer

payment to FDA Action Center (FDAC) through email.				
	3.2 CDRRHR assigns the application to evaluator	None	1 Working day	CDRRHR Admin Staff
	3.3 The technical evaluator reviews the application. Recommends approval or disapproval.	None	7 working days	Technical Evaluator
	3.4 Quality Assurance - Checking of recommendation of the Supervisor	None	5 working days	LRD Chief
	3.5 Assigning of numbers and Printing of certificates.	None	2 working days	Technical Evaluator
	3.6 Final Approval/Disapproval and signature of the Director.	None	2 working days	CDRRHR Director
	3.7 Scanning and transmitting of certificates to the Record Section.	None	2 working days	CDRRHR Administrative Staff
4. Pick-up of Certificate	4 Queuing and endorsement to FDA Releasing Section	None	1 working day	AFS Records Officer / Administrative Officer
	TOTAL	PHP510.00	20 working days**	

*Day 1 commences upon the receipt of the proof of payment / posting of payment.

**Timeline provided is for applications that are complete and correct with no Notice of Deficiencies issued.

9.ISSUANCE OF CERTIFICATE OF MEDICAL DEVICE LISTING (CMDL)

The application for authorization issued for a medical device that is intended for research, clinical trial, exhibit, donation, etc. and that is not intended for sale.

Center/Office/Division	:	CDRRHR-LRD
Classification	:	Complex Transaction
Type of Transaction	:	G2B - Government-to-Businesses
Who May Avail	:	Medical Device Manufacturers/Distributors (Importer/Exporter/Wholesaler)/Trader
Fees to be Paid	:	Php 500.00 + 1% LRF per certificate Note: Fee is per product reflected in a single packing list or invoice. If the product is reflected on a separate packing list/invoice, an additional fee shall be required.

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
LEGAL REQUIREMENTS	
Duly notarized and completely filled-up scanned copy of the Application Form.	Applicant. Form may be downloaded from the FDA website.
Notarized letter addressed to the Director, Center for Device Regulation, Radiation Health, and Research, stating that the medical device will be used solely for the intended use (e.g., research, clinical investigation, exhibit, personal use, sample product for analysis/testing, or donated brand new medical devices) and is not intended for sale. The letter should contain the following information: Complete list of the devices indicating the quantity, brand and the name of the manufacturer of the product Declaration that the organization shall be the sole entity responsible for the medical devices and that the CDRRHR-FDA, DOH will not be held liable for any safety issue concerning the product.	Applicant company

3. Copy of Certificate of Product Notification or Certificate of Product Registration or any equivalent document attesting to the safety and effectiveness of the device issued by the regulatory agency in the country where the device will come from.	Principal/Source/Manufacturer
4 Copy of SEC or DTI registration, when applicable.	Applicant company
5 Details for Bill of Landing Number / Air Waybill; Container Numbers, Packing List Number/Invoice Number.	Principal/Source/Manufacturer
6 For donated medical device/s (brand new), a certified true copy of the deed of donation and the deed of acceptance.	Principal/Source/Manufacturer and Applicant Company
7 For research proposal, research approval from Ethics Committee and research protocol.	Applicant company
8 For clinical study, approval from the Ethics Committee and clinical study protocol.	Applicant company
6. Payment	Applicant company
Submit an electronic/scanned copy (in PDF searchable format of at least 150 dpi) The file name should consist of the name of the requirement.	

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME*	PERSON RESPONSIBLE
1. The applicant company sends an email to FDAC Letters. The e-mail should contain the complete application requirements.**	1. Receiving officer generates a Document Tracking Number (DTN) and sends an acknowledgment email / order of payment to the client.	None		FDAC Officer
2. The applicant company receives the Order of Payment and pays the assessed fee through FDAC Cashier or any other means prescribed by FDA. (e.g.	FDA receives the payment from the applicant company for posting.	PHP 510.00 per product. Note: If the declared products for importation are	Timeline starts after posting of payment	FDA Cashier

BANCNET, LANDBANK ONCOLL). The Order of Payment will only be valid for 24 hours.		reflected on different or separate packing list/invoice, then an additional payment of PHP510.00 per invoice would be required.		
3. The applicant company receives the official receipt and sends the proof of payment to FDA Action Center (FDAC) through email.	3.1 FDAC forwards the application to CDRRHR.	None	1 working day	FDAC Officer
	3.2. CDRRHR assigns the application to evaluator	None	1 working day	CDRRHR Administrative Staff
	3.3. The technical evaluator reviews the application. Recommends approval or disapproval. Assigns the number and prints the CMDL.	None	8 working days	Technical Evaluator
	3.4. Quality Assurance - Checking of recommendation of the Supervisor	None	5 working days	LRD Chief
	3.5. Final Approval/Disapproval and signature of the Director.	None	2 working days	CDRRHR Director
	3.6. Scanning and transmitting of CMDL to the Records Section.	None	2 working days	CDRRHR Administrative Staff
4. Pick-up of certificate	4. Queuing and endorsement to the FDA Releasing Section	None	1 working day	AFS Records Officer

				/ Administrative Officer
	TOTAL	PHP510.00 per product/packing list/invoice	20 working days	

*Day 1 commences upon the receipt of the proof of payment / posting of payment.

**Refer to FDA Circular No. 2020-026 – Food and Drug Action Center (FDAC) New Normal Operational Guidelines of the Food and Drug Administration (FDA).

10.ISSUANCE OF CERTIFICATE OF MEDICAL DEVICE NOTIFICATION (INITIAL APPLICATION)

The application for authorization issued for medical devices that fall under Class A.

Center/Office/Division	:	CDRRHR-LRD
Classification	:	Highly Technical
Type of Transaction	:	G2B - Government-to-Businesses
Who May Avail	:	Medical Device Manufacturers/Distributors (Importer/Exporter/Wholesaler)/Trader
Fees to be Paid	:	Php7,500.00 + 1% LRF for initial with 5-year validity for Class A medical devices Php3,000.00 + 1% LRF for initial with 2-year validity for Class B, C, D medical devices not included in FDA Circular 2020-001-A

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
LEGAL REQUIREMENTS	
1 copy of Notarized Agreement / Letter of Authorization. Must be valid; The product being applied must be indicated. For imported medical devices, with notarized declaration from the legal manufacturer or product owner attesting that the authorization / agreement is true and correct. For imported medical devices but the agreements are signed in the Philippines, it must be notarized locally, with passport ID page and record of arrival and departure of the principal to and from the Philippines of the signatory/ies, and must be signed by both parties. For open-dated agreements/authorizations, if the certificate is beyond the 5-year period from the document's issuance, a re-issued agreement/authorization or a notarized attestation by the Principal that the agreement/authorization is still in effect must be submitted. For locally manufactured medical devices with an exclusive distributor, the agreement should be duly notarized. For locally manufactured medical devices with a toll manufacturer, the agreement between the trader and the manufacturer should be duly notarized.	Principal/Source/Manufacturer

2. For Imported Medical Devices - 1 copy of government-issued certificate attesting to the status of the Manufacturer with regard to the competence and reliability of the personnel and facilities, a Quality Systems Certificate of approval, or a compliance certificate for ISO 13485. Must be valid Copy of the certificate shall be accompanied by a notarized declaration from the legal manufacturer or product owner attesting that the certificate is true and correct. For products that are manufactured in multiple sites or toll manufacturers, identify or highlight the product source. The product being applied must be indicated in the scope. For locally manufactured products, submit the valid LTO of the manufacturer	Principal/Source/Manufacturer
For imported medical devices, 1 copy of Certificate of Product Notification, Certificate of Product Registration, or any equivalent document attesting to the safety and effectiveness of the device issued by the manufacturer (Self-Declaration), regulatory agency or accredited notified body in the country of origin. Must be valid The copy of the certificate shall be accompanied by a notarized declaration from the legal manufacturer or product owner attesting that the certificate is true and correct. Authenticated or apostilled document can be accepted if the document is authenticated or apostilled prior to September 2020.	Principal/Source/Manufacturer
4. 1 Clear colored picture of the actual commercial product sample of the device for all sides without its packaging. An actual representative sample or commercial presentation can be required by the CDRRHR for verification purposes. Picture should not pixelate when the view is increased in size	Principal/Source/Manufacturer
TECHNICAL REQUIREMENTS	

. Device Description consisting of the following: Intended use – this should include the specific use of the product being applied. If the product is part of the system, the specific use of the product as part of the system should be indicated and not the intended use of the system. Instruction for use – this is the detailed instruction for use for the users of the medical device. The instruction should be clear enough to guide its users. List of raw materials – this should include all the raw materials as a component of the medical device itself. For kits/sets: submit the raw materials used with specifications of all components in the kit/set. For machines/equipment: The list of raw materials is ONLY required for the machine parts/accessories that: 1) will have a direct contact with the patient; and/or 2) will serve as a channel/conduit for medical gases during infusion (i.e. ventilators) - parts that come in direct contact with medical gases for infusion. Technical specification of the finished product – This should include the technical specification of the finished products (physical, chemical, mechanical, electrical, etc.). This may be in the form of Certificate of Analysis or Test certificate. For locally manufactured devices, the hierarchy of product standards shall apply.	Principal/Source/Manufacturer
1 copy of Certificate of Conformity (issued by the government agency, or its equivalent, dealing with metrology) on the aspect of manufacture relating to metrology for devices with measuring functions, if applicable i.e. Thermometer, Weighing Scale, etc.	Principal/Source/Manufacturer
Declaration of Conformity with product standards (self-declaration by the manufacturer) with list of product standards. These are the standards used during the design, development, manufacture, testing of the medical devices. The following standards shall be considered: Philippine National Standards (PNS), international standards (ISO, IEC), other International Standard Bodies recognized by the DOH and other equivalent national standards (of these international standards).	Manufacturer

Clear and complete colored pictures of label from all sides of the packaging (loose label or artworks of all layers of packaging) for all codes included in the application. Immediate label, secondary packaging, box label and package insert/brochure, whichever is applicable. For any additional product claims on the label, submit studies or tests supporting the claims. For imported products, if the brand name is the product's local brand, declaration from the manufacturer allowing use of the brand name and IPO approval of the said brand name. For local manufactured products, IPO approval of the brand name If the CE marking is reflected on the label, submit a valid certificate supporting the placement of the CE mark. Pictures and text of the label should be clear and will not be pixelated when the view is increased in size. Lot No., Batch No., Serial No., whichever is applicable should be reflected. Expiration date, reference codes/sizes/variants/model whichever is applicable should be reflected. Storage condition, sterilization method should be reflected if applicable. Importer and distributor's name and address should be reflected in the label of the product together with the Product Notification Number Suggested Retail Price (SRP) in Philippine peso Note: The above requirements shall be superseded upon the approval of Administrative Order for the labeling requirements of medical devices.	Principal/Source/Manufacturer
9. Declaration of shelf life.	Manufacturer
10. Payment	FDA Cashier
All documents must be submitted in the English language. Documents submitted in any other foreign language not accompanied by a notarized English translation for legal documents and an English translation for technical documents shall be disapproved. Documents should be in PDF searchable format of at least 150 dpi. The file name should consist of the name of the requirement.	

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME*	PERSON RESPONSIBLE
1. The applicant company will request for the user account through email.	1.FDA issues user account	None		FDAC Officer
2. The authorized representative of the applicant company fills out the online form/e-notification through the portal (eportal.fda.gov.ph). Uploads all the documents indicated on the checklist.	2.The CDRRHR assigns the application to the evaluator for pre-assessment. Applications filed from 5:00 PM and beyond will be decked for pre-assessment the next working day (8:00 AM).	None		CDRRHR Administrative Staff
3. If all the requirements are deemed complete, the applicant company receives the Order of Payment and pays the assessed fee through FDAC Cashier or any other means prescribed by FDA. (e.g. BANCNET, LANDBANK ONCOLL). The Order of Payment will only be valid for 5 working days.	3. Pre-assessment the application. The Client will receive either Order of Payment or Letter of Denial	None		CDRRHR Evaluator
4. The applicant company receives the official receipt.	4.1 FDA receives the payments from the applicant company. Posting of payment and automatic decking of the application to CDRRHR.	Php 7,575.00 or Php 3,030.00	Timeline starts after posting of payment	FDA Cashier

	4.2 Evaluation of application.	None	10 working days	
	4.3 Quality Assurance - Checking of recommendation of the Supervisor	None	10 working days	LRD Chief
	4.4 Final Approval/Disapproval with e-signature of the Director.	None	5 working days	CDRRHR Director
	TOTAL	PHP 7,575.00 or Php 3,030.00	25 working days**	

*Day 1 commences upon the receipt of the proof of payment / posting of payment.

**Service is covered under Republic Act No. 3720 Section 21 as amended by Executive Order No. 175 Section 13.

11.ISSUANCE OF CERTIFICATE OF MEDICAL DEVICE REGISTRATION (CMDR) FOR CLASS B (ABRIDGED APPROVAL, INITIAL APPLICATION)

The registration of Class B medical devices with product approval issued by the NRA of any ASEAN-member country under the AMDD-CSDT requirements, and which are to be imported, distributed, and sold in the Philippines. This shall not cover medical devices with issued Certificate of Product Registration (CPR) based on abridged approval in other countries outside the ASEAN.

Center/Office/Division	:	CDRRHR-LRD
Classification	:	Highly Technical
Type of Transaction	:	G2B - Government-to-Businesses
Who May Avail	:	Medical Device Manufacturers/Distributors (Importer/Exporter/Wholesaler)/Trader
Fees to be Paid	:	Php7,500.00 + 1% LRF for initial with 5-year validity (Php. 7,575.00) per product

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
Notarized Application Form Must be completely and correctly filled-up and signed Must use the latest form prescribed by the CDRRHR for the type of application Must submit one application form with attachment reflecting all the product codes being applied. Furthermore, the grouping of medical device family should be clearly specified. Only one condition should be considered in the multiple CPR application. Must be unedited, non-tampered; and must reflect the correct brand name, medical device name, and device risk-classification.	Applicant. Form may be downloaded from the FDA website.

1 copy of Notarized Agreement / Letter of Authorization. Must be valid; The product being applied must be indicated. For imported medical devices, with notarized declaration from the legal manufacturer or product owner attesting that the authorization / agreement is true and correct. For imported medical devices but the agreement is signed in the Philippines, it must be notarized locally, with passport ID page and record of arrival and departure of the principal to and from the Philippines of the signatory/ies, and must be signed by both parties. For open-dated agreements/authorizations, if the certificate is beyond the 5-year period from the document's issuance, a re-issued agreement/authorization or a notarized attestation by the Principal that the agreement/authorization is still in effect must be submitted. For locally manufactured medical devices with exclusive distributors, the agreement should be duly notarized. For locally manufactured medical devices with a toll manufacturer, the agreement between the trader and the manufacturer should be duly notarized.	Principal/Source/Manufacturer
For Imported Medical Devices - 1 copy of government-issued certificate attesting to the status of the Manufacturer with regard to the competence and reliability of the personnel and facilities, a Quality Systems Certificate of approval, or a compliance certificate for ISO 13485. Must be valid Copy of the certificate shall be accompanied by a notarized declaration from the legal manufacturer or product owner attesting that the certificate is true and correct. For products that are manufactured in multiple sites or toll manufacturers, identify or highlight the product source. The product being applied must be indicated in the scope. For locally manufactured products, submit the valid LTO of the manufacturer	Principal/Source/Manufacturer
For imported medical devices, 1 copy of the product approval issued by the NRA of any ASEAN-member country under the AMDD-CSDT requirements. ***** Must be valid	Principal/Source/Manufacturer

The copy of the certificate shall be accompanied by a notarized declaration from the legal manufacturer or product owner attesting that the certificate is true and correct.	
Clear colored picture of the actual commercial product sample of the device for all sides without its packaging, for all codes included in the application. An actual representative sample or commercial presentation can be required by the CDRRHR for verification purposes. Pictures should not be pixelated when the view is increased in size.	Principal/Source/Manufacturer
Technical Requirements	
Executive Summary. The executive summary shall include the following information: an overview, e.g., introductory descriptive information on the medical device, the intended uses and indications for use of the medical device, any novel features, and a synopsis of the content of the CSDT; the commercial marketing history; the list of regulatory approvals or marketing clearances obtained; the status of any pending request for market clearance; and the important safety/performance related information.	Applicant or Principal/Source/Manufacturer
Relevant essential principles and method/s used to demonstrate conformity. Must be completely filled-up	Principal/Source/Manufacturer

Device description with the following information: Intended use- this refers to the use for which the medical device is intended, for which it is suited according to the data supplied by the product owner in the instructions as well as the functional capability of the medical device. If the product is part of the system, the specific use of the product as part of the system should be indicated and not the intended use of the system. Indications of use- this is a general description of the disease or condition that the medical device will diagnose, treat, prevent, cure or mitigate; and includes a description of the target patient population for which the medical device is intended. Instruction for use- these are all necessary information from the product owner including the procedures, methods, frequency, duration, quantity and preparation to be followed for sale use of the medical device, instructions needed to use the medical device in a safe manner shall, to the extent possible, be included on the medical device itself and/or its packaging by other formats/forms. This is the detailed instruction for use for the users of the medical device. The instruction should be clear enough to guide its users. Contraindications- This is a general description of the disease or condition and the patient population for which the medical device should not be used for the purpose of diagnosing, treating, curing or mitigating. Contraindications are conditions under which the medical device should not be used because the risk of use clearly outweighs any possible benefit Warnings - This is the specific hazard alert information that the user needs to know before using the medical device.	Principal/Source/Manufacturer

Precautions-This alerts the user to exercise special care necessary for the safe and effective use of the medical device. This may include actions to be taken to avoid effects on patients/users that may not be potentially life threatening or result in serious injury, but about which the user should be aware. Precautions may also alert the user to adverse effects on the medical device of use or misuse and the care necessary to avoid such effects. Potential adverse effects- These are potential undesirable and serious outcomes (death, injury, or serious adverse events) to the patient/user, or side effects from the use of the medical device, under normal conditions. Alternative therapy (practices and procedures) (if applicable) - This is a description of any alternative practices or procedures for diagnosing, treating, curing or mitigating the disease or condition for which the medical device is intended. Raw Materials or formulation. A description of the materials or formulation of the device and their physical properties to the extent necessary to demonstrate conformity with the relevant Essential Principles. The information shall include complete chemical, biological and physical characterization of the materials of the device. Should have a List of all raw materials used as a component of the product (specify for which product part or component the raw material is used) Must include quantity (for solutions) and technical specifications or detailed information on physical and chemical properties of each component. If the device contains PVC, identify the PVC plasticizer used. For kits/sets: submit the raw materials used with specifications of all components in the kit/set. For machines/equipment: The list of raw materials is ONLY required for the machine parts/accessories that: 1) will have a direct contact with the patient; and/or 2) will serve as a channel/conduit for medical	

gases during infusion (i.e. ventilators) - parts that come in direct contact with medical gases for infusion. Other Relevant Specifications to include the following: The functional characteristics and technical performance specifications of the device including, as relevant: accuracy, sensitivity, specificity of measuring and diagnostic medical devices, reliability, and other factors Other specifications including chemical, physical, electrical, mechanical, biological, software, sterility, stability, storage and transport, and packaging. May submit Certificate of Analysis or Test Certificate with finished product specification. For Stability, submit functionality and packaging/integrity test study of the product duly signed by the person who conducted the studies to justify the claimed expiration date. For accelerated study, submit computation to justify the storage conditions used. If no expiration, submit justification from the manufacturer why the device has no expiration. Submit in-use stability study, as applicable. (e.g. contact lens solution, disinfectant) Identify the product's storage condition. For products with special storage conditions, submit transport stability study. For packaging, clarify the type of packaging used. i.e. blister pack, carton box, etc. For medical devices with animal tissue origin, submit Certificate of Compliance with ISO 22442 - Medical devices utilizing animal tissues and their derivatives issued by Government Authority or notified body. Other Descriptive Information to demonstrate conformity with the relevant Essential Principles (e.g. biocompatibility category for the finished medical device)	

Summary of Design Verification and Validation Documents: The validation documents shall consist of the following: Declaration/Certificates of Conformity to the product standards issued by the manufacturer Summaries or reports of tests and evaluation based on other standards, manufacturer methods and tests, or alternative ways of demonstrating compliance covering the following appropriate tests reports and evaluations, whichever is applicable: a listing of and conclusions drawn from published reports that concern the safety and performance of aspects of the medical device with reference to the Essential Principles; Engineering test Laboratory test Biocompatibility test Animal Test Simulated Use software validation Pre-clinical studies The following standards shall be considered: Philippine National Standards (PNS), international standards (ISO, IEC) and other equivalent national standards (of these international standards). Philippine National Standard (PNS) ISO Standard or IEC Standard (whichever is applicable) in the absence of PNS. Standard developed by other International Standard Bodies recognized by the DOH, in the absence of PNS, ISO Standard, and IEC Standard. Any foreign standard that may be recognized by the DOH for the purpose of registration in the absence of PNS, ISO Standard, and IEC Standard, and standard developed by other International Standard Bodies recognized by the DOH.	Principal/Source/Manufacturer

. Clear and complete colored pictures of label from all sides of the packaging (loose label or artworks of all layers of packaging) Immediate label, secondary packaging, box label and package insert/brochure, whichever is applicable. For any additional product claims on the label, submit studies or tests supporting the claims. For imported products, if the brand name is the product's local brand, declaration from the manufacturer allowing use of the brand name and IPO approval of the said brand name. For local manufactured products, IPO approval of the brand name If the CE marking is reflected on the label, submit a valid certificate supporting the placement of the CE mark. Pictures and text of the label should be clear and not be pixelated when the view is increased in size. Lot No., Batch No., Serial No., whichever is applicable, should be reflected. Expiration date, reference codes/sizes/variants/model whichever is applicable should be reflected. Storage condition, sterilization method should be reflected if applicable. Importer and distributor's name and address should be reflected in the label of the product together with the Registration Number. Suggested Retail Price (SRP) in Philippine peso. The above requirements shall be superseded upon the approval of Administrative Order for the labeling requirements for medical devices.	Applicant or Principal/Source/Manufacturer
. Risk Analysis to include the results Identify the risk Submit Failure Mode Effect Analysis / Risk Benefit Analysis	Principal/Source/Manufacturer

. Physical Manufacturer information Manufacturing process, including quality assurance measures. This should include the manufacturing methods and procedures, manufacturing environment or conditions, facilities and controls. The information may be presented in the form of a process flow chart showing an overview of production, controls, assembly, final product testing, and packaging of finished medical device. A brief summary of the sterilization method should be included. Include sterilization standard parameters, sterilization procedures, validation protocol and results of latest sterilization revalidation. If the sterilization of the device is contracted out, submit a copy of valid ISO Certificate of the contracted sterilizing company. For non-sterile devices: a) submit Non-sterile declaration from the manufacturer; b) If the device is required to be sterilized prior to use, submit recommended sterilization guidelines from the manufacturer.	Principal/Source/Manufacturer
Payment	FDA Cashier
Documentary requirements must be arranged according to the CSDT format. All documents must be submitted in English language. Documents submitted in any other foreign language not accompanied by a notarized English translation for legal documents and an English translation for technical documents shall be disapproved. Documents to be uploaded should be in PDF searchable format of at least 150 dpi The file name to be uploaded should consist of the name of the requirements Provide table of contents with page number	

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME**	PERSON RESPONSIBLE
1. Client sends an email containing the PDF file of their application to cdrrhr-productregistration@fda.gov.ph	1.1 Receiving officer sends an acknowledgment email to the client and decks the application to the evaluator for pre-assessment.	None		CDRRHR Officer

following the correct schedule of application.				
	1.2 Pre-assessment and issuance of Order of Payment or Denial Letter.	None		Technical Evaluator
2. The applicant company receives the Order of Payment and pays the assessed fee through FDAC Cashier or any other means prescribed by FDA. (e.g. BANCNET, LANDBANK ONCOLL). The Order of Payment will only be valid for 3 working days.	2 FDA receives the payment from the applicant company for posting	Php 7,575.00	Timeline starts after posting of payment	FDA Cashier
3 The applicant company receives the official receipt and sends the proof of payment to cdrrhr-productregistration@fda.gov.ph	3.1 CDRRHR assigns the application to evaluator	None	1 working day	CDRRHR Administrative Staff
	3.2 The technical evaluator reviews the application. Recommends approval or disapproval.	None	8 working days***	Technical Evaluator
	3.3 Quality Assurance - Checking of recommendation of the Supervisor	None	3 working days	LRD Chief
	3.4 Drafting and finalization of CPR.	None	2 working days	Technical Evaluator

	3.5 Final Approval/Disapproval and E-Signature	None	2 working days	CDRRHR Director
	3.6 Assigning of number and Printing of CMDR. Scanning, barcoding and transmitting of CMDR to the Records Section.		3 working days	CDRRHR Administrative Staff
	3.7 Queuing and endorsement to the FDA Releasing Section		1 working day	AFS Records Officer/Administrative Officer
	TOTAL	Php 7,575.00	20 working days****	

*Refer to the FDA Advisory No. 2021-3084 – Abridged Processing of Applications for Registration/Notification of Medical Devices Approved by the Regulatory Authority of any ASEAN Member Country.

**Day 1 commences upon the receipt of the proof of payment / posting of payment.

***Timeline provided is for applications that are complete and correct with no Notice of Deficiencies issued.

****Service is covered under Republic Act No. 3720 Section 21 as amended by Executive Order No. 175 Section 13.

*****FDA Circular No. 2022-008: Abridged Processing of Application for Registration of Medical Devices Approved by the National Regulatory Authority of Any ASEAN Member Country

12.ISSUANCE OF CERTIFICATE OF MEDICAL DEVICE REGISTRATION (CMDR) FOR CLASS B (INITIAL APPLICATION)

The application for authorization issued for medical devices that fall under Class B.

Center/Office/Division	:	CDRRHR-LRD
Classification	:	Highly Technical
Type of Transaction	:	G2B - Government-to-Businesses
Who May Avail	:	Medical Device Manufacturers/Distributors (Importer/Exporter/Wholesaler)/Trader
Fees to be Paid	:	Php7,500.00 + 1% LRF for initial with 5-year validity (Php. 7,575.00) per product

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
Notarized Application Form Must be completely and correctly filled-up and signed Must use the latest form prescribed by the CDRRHR for the type of application Must submit one application form with attachment reflecting all the product codes being applied. Furthermore, the grouping of medical device family should be clearly specified. Only one condition should be considered in the multiple CPR application. Must be unedited, non-tampered; and must reflect the correct brand name, medical device name, and device risk-classification.	Applicant. Form may be downloaded from the FDA website.

1 copy of Notarized Agreement / Letter of Authorization. Must be valid; The product being applied must be indicated. For imported medical devices, with notarized declaration from the legal manufacturer or product owner attesting that the authorization / agreement is true and correct. For imported medical devices but the agreement is signed in the Philippines, it must be notarized locally, with passport ID page and record of arrival and departure of the principal to and from the Philippines of the signatory/ies, and must be signed by both parties. For open-dated agreements/authorizations, if the certificate is beyond the 5-year period from the document's issuance, a re-issued agreement/authorization or a notarized attestation by the Principal that the agreement/authorization is still in effect must be submitted. For locally manufactured medical devices with exclusive distributors, the agreement should be duly notarized. For locally manufactured medical devices with a toll manufacturer, the agreement between the trader and the manufacturer should be duly notarized.	Principal/Source/Manufacturer
For Imported Medical Devices - 1 copy of government-issued certificate attesting to the status of the Manufacturer with regard to the competence and reliability of the personnel and facilities, a Quality Systems Certificate of approval, or a compliance certificate for ISO 13485. Must be valid Copy of the certificate shall be accompanied by a notarized declaration from the legal manufacturer or product owner attesting that the certificate is true and correct. For products that are manufactured in multiple sites or toll manufacturers, identify or highlight the product source. The product being applied must be indicated in the scope. For locally manufactured products, submit the valid LTO of the manufacturer	Principal/Source/Manufacturer

4 For imported medical devices, 1 copy of Certificate of Product Registration, CE Certificate or any equivalent document attesting to the safety and effectiveness of the device issued by regulatory agency or accredited notified body in the country of origin. Must be valid The copy of the certificate shall be accompanied by a notarized declaration from the legal manufacturer or product owner attesting that the certificate is true and correct.	Principal/Source/Manufacturer
Clear colored picture of the actual commercial product sample of the device for all sides without its packaging, for all codes included in the application. An actual representative sample or commercial presentation can be required by the CDRRHR for verification purposes. Pictures should not be pixelated when the view is increased in size.	Principal/Source/Manufacturer
Technical Requirements	
Executive Summary. The executive summary shall include the following information: an overview, e.g., introductory descriptive information on the medical device, the intended uses and indications for use of the medical device, any novel features, and a synopsis of the content of the CSDT; the commercial marketing history; the list of regulatory approvals or marketing clearances obtained; the status of any pending request for market clearance; and the important safety/performance related information.	Applicant or Principal/Source/Manufacturer
Relevant essential principles and method/s used to demonstrate conformity. Must be completely filled-up	Principal/Source/Manufacturer

Device description with the following information: Intended use- this refers to the use for which the medical device is intended, for which it is suited according to the data supplied by the product owner in the instructions as well as the functional capability of the medical device. If the product is part of the system, the specific use of the product as part of the system should be indicated and not the intended use of the system. Indications of use- this is a general description of the disease or condition that the medical device will diagnose, treat, prevent, cure or mitigate; and includes a description of the target patient population for which the medical device is intended. Instruction for use- these are all necessary information from the product owner including the procedures, methods, frequency, duration, quantity and preparation to be followed for sale use of the medical device, instructions needed to use the medical device in a safe manner shall, to the extent possible, be included on the medical device itself and/or its packaging by other formats/forms. This is the detailed instruction for use for the users of the medical device. The instruction should be clear enough to guide its users. Contraindications- This is a general description of the disease or condition and the patient population for which the medical device should not be used for the purpose of diagnosing, treating, curing or mitigating. Contraindications are conditions under which the medical device should not be used because the risk of use clearly outweighs any possible benefit. Warnings-This is the specific hazard alert information that the user needs to know before using the medical device.	Principal/Source/Manufacturer

Precautions-This alerts the user to exercise special care necessary for the safe and effective use of the medical device. This may include actions to be taken to avoid effects on patients/users that may not be potentially life threatening or result in serious injury, but about which the user should be aware. Precautions may also alert the user to adverse effects on the medical device of use or misuse and the care necessary to avoid such effects. Potential adverse effects- These are potential undesirable and serious outcomes (death, injury, or serious adverse events) to the patient/user, or side effects from the use of the medical device, under normal conditions. Alternative therapy (practices and procedures) (if applicable) - This is a description of any alternative practices or procedures for diagnosing, treating, curing or mitigating the disease or condition for which the medical device is intended. Raw Materials or formulation. A description of the materials or formulation of the device and their physical properties to the extent necessary to demonstrate conformity with the relevant Essential Principles. The information shall include complete chemical, biological and physical characterization of the materials of the device. Should have a List of all raw materials used as a component of the product (specify for which product part or component the raw material is used) Must include quantity (for solutions) and technical specifications or detailed information on physical and chemical properties of each component. If the device contains PVC, identify the PVC plasticizer used. For kits/sets: submit the raw materials used with specifications of all components in the kit/set. For machines/equipment: The list of raw materials is ONLY required for the machine parts/accessories that: 1) will have a direct contact with the patient; and/or 2) will serve as a	

channel/conduit for medical gases during infusion (i.e. ventilators) - parts that come in direct contact with medical gases for infusion. Other Relevant Specifications to include the following: The functional characteristics and technical performance specifications of the device including, as relevant: accuracy, sensitivity, specificity of measuring and diagnostic medical devices, reliability, and other factors Other specifications including chemical, physical, electrical, mechanical, biological, software, sterility, stability, storage and transport, and packaging. May submit Certificate of Analysis or Test Certificate with finished product specification. For Stability, submit functionality and packaging/integrity test study of the product duly signed by the person who conducted the studies to justify the claimed expiration date. For accelerated study, submit computation to justify the storage conditions used. If no expiration, submit justification from the manufacturer why the device has no expiration. Submit in-use stability study, as applicable. (e.g. contact lens solution, disinfectant) Identify the product's storage condition. For products with special storage conditions, submit transport stability study. For packaging, clarify the type of packaging used. i.e. blister pack, carton box, etc. For medical devices with animal tissue origin, submit Certificate of Compliance with ISO 22442 - Medical devices utilizing animal tissues and their derivatives issued by Government Authority or notified body. Other Descriptive Information to demonstrate conformity with the relevant Essential Principles (e.g. biocompatibility category for the finished medical device)	

Summary of Design Verification and Validation Documents: The validation documents shall consist of the following: Declaration/Certificates of Conformity to the product standards issued by the manufacturer Summaries or reports of tests and evaluation based on other standards, manufacturer methods and tests, or alternative ways of demonstrating compliance covering the following appropriate tests reports and evaluations, whichever is applicable: a listing of and conclusions drawn from published reports that concern the safety and performance of aspects of the medical device with reference to the Essential Principles; Engineering test Laboratory test Biocompatibility test Animal Test Simulated Use software validation Pre-clinical studies The following standards shall be considered: Philippine National Standards (PNS), international standards (ISO, IEC) and other equivalent national standards (of these international standards). Philippine National Standard (PNS) ISO Standard or IEC Standard (whichever is applicable) in the absence of PNS. Standard developed by other International Standard Bodies recognized by the DOH, in the absence of PNS, ISO Standard, and IEC Standard. Any foreign standard that may be recognized by the DOH for the purpose of registration in the absence of PNS, ISO Standard, and IEC Standard, and standard developed by other International Standard Bodies recognized by the DOH.	Principal/Source/Manufacturer

Clear and complete colored pictures of label from all sides of the packaging (loose label or artworks of all layers of packaging) Immediate label, secondary packaging, box label and package insert/brochure, whichever is applicable. For any additional product claims on the label, submit studies or tests supporting the claims. For imported products, if the brand name is the product's local brand, declaration from the manufacturer allowing use of the brand name and IPO approval of the said brand name. For local manufactured products, IPO approval of the brand name If the CE marking is reflected on the label, submit a valid certificate supporting the placement of the CE mark. Pictures and text of the label should be clear and not be pixelated when the view is increased in size. Lot No., Batch No., Serial No., whichever is applicable, should be reflected. Expiration date, reference codes/sizes/variants/model whichever is applicable should be reflected. Storage condition, sterilization method should be reflected if applicable. Importer and distributor's name and address should be reflected in the label of the product together with the Registration Number. Suggested Retail Price (SRP) in Philippine peso. The above requirements shall be superseded upon the approval of Administrative Order for the labeling requirements for medical devices.	Applicant or Principal/Source/Manufacturer
Risk Analysis to include the results Identify the risk Submit Failure Mode Effect Analysis / Risk Benefit Analysis	Principal/Source/Manufacturer

Physical Manufacturer information Manufacturing process, including quality assurance measures. This should include the manufacturing methods and procedures, manufacturing environment or conditions, facilities and controls. The information may be presented in the form of a process flow chart showing an overview of production, controls, assembly, final product testing, and packaging of finished medical device. A brief summary of the sterilization method should be included. Include sterilization standard parameters, sterilization procedures, validation protocol and results of latest sterilization revalidation. If the sterilization of the device is contracted out, submit a copy of valid ISO Certificate of the contracted sterilizing company. For non-sterile devices: a) submit Non-sterile declaration from the manufacturer; b) If the device is required to be sterilized prior to use, submit recommended sterilization guidelines from the manufacturer.	Principal/Source/Manufacturer
Payment	FDA Cashier
Documentary requirements must be arranged according to the CSDT format. All documents must be submitted in English language. Documents submitted in any other foreign language not accompanied by a notarized English translation for legal documents and an English translation for technical documents shall be disapproved. Documents to be uploaded should be in PDF searchable format of at least 150 dpi The file name to be uploaded should consist of the name of the requirements Provide table of contents with page number	

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME*	PERSON RESPONSIBLE
1. Client sends an email containing the PDF file of their application to cdrrhr-productregistration@fda.gov.ph	1.1 Receiving officer sends an acknowledgment email to the client and decks the application to the evaluator for pre-assessment.	None		CDRRHR Officer

following the correct schedule of application.				
	1.2 Pre-assessment and issuance of Order of Payment or Denial Letter.	None		Technical Evaluator
2. The applicant company receives the Order of Payment and pays the assessed fee through FDAC Cashier or any other means prescribed by FDA. (e.g. BANCNET, LANDBANK ONCOLL) The Order of Payment will only be valid for 3 working days.	2 The FDA receives the payment from the applicant company for posting	Php 7,575.00	Timeline starts after posting of payment	FDA Cashier
3 The applicant company receives the official receipt and sends the proof of payment to cdrrhr-productregistration@fda.gov.ph	3.1 The CDRRHR assigns the application to evaluator	None	2 working days	CDRRHR Administrative Staff
	3.2 The technical evaluator reviews the application. Recommends approval or disapproval.	None	53 working days*	Technical Evaluator
	3.3 Quality Assurance - Checking of recommendation of the Supervisor	None	10 working days	LRD Chief
	3.4 Drafting and finalization of CPR.	None	3 working days	Technical Evaluator

	3.5 Final Approval/Disapproval and E-Signature	None	5 working days	CDRRHR Director
	3.6 Assigning of number and Printing of CMDR. Scanning, barcoding and transmitting of CMDR to the Records Section.		6 working days	CDRRHR Administrative Staff
	3.7 Queuing and endorsement to the FDA Releasing Section		1 working day	AFS Records Officer / Administrative Officer
	TOTAL:	Php 7,575.00	80 working days***	

*Day 1 commences upon the receipt of the proof of payment / posting of payment.

**Timeline provided is for applications that are complete and correct with no Notice of Deficiencies issued.

***Service is covered under Republic Act No. 3720 Section 21 as amended by Executive Order No. 175 Section 13.

13.ISSUANCE OF CERTIFICATE OF MEDICAL DEVICE REGISTRATION (CMDR) FOR CLASS C AND D (ABRIDGED APPROVAL, INITIAL APPLICATION)

The registration of Class C and D medical devices with product approval issued by the NRA of any ASEAN-member country under the AMDD-CSDT requirements, and which are to be imported, distributed, and sold in the Philippines. This shall not cover medical devices with issued Certificate of Product Registration (CPR) based on abridged approval in other countries outside the ASEAN.

Center/Office/Division	:	CDRRHR-LRD
Classification	:	Highly Technical
Type of Transaction	:	G2B - Government-to-Businesses
Who May Avail	:	Medical Device Manufacturers/Distributors (Importer/Exporter/Wholesaler)/Trader
Fees to be Paid	:	Php7,500.00 + 1% LRF for initial with 5-year validity (Php. 7,575.00) per product

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
Notarized Application Form Must be completely and correctly filled-up and signed Must use the latest form prescribed by the CDRRHR for the type of application Must submit one application form with attachment reflecting all the product codes being applied. Furthermore, the grouping of medical device family should be clearly specified. Only one condition should be considered in the multiple CPR application. Must be unedited, non-tampered; and must reflect the correct brand name, medical device name, and device risk-classification.	Applicant. Form may be downloaded from the FDA website.

1 Copy of Notarized Agreement / Letter of Authorization. Must be valid; For imported medical devices, with notarized declaration from the legal manufacturer or product owner attesting that the authorization / agreement is true and correct. For imported medical devices but the agreements are signed in the Philippines, it must be notarized locally, with passport ID page and record of arrival and departure of the principal to and from the Philippines of the signatory/ies, and must be signed by both parties. For open-dated agreements/authorizations, if the certificate is beyond the 5-year period from the document's issuance, a re-issued agreement/authorization or a notarized attestation by the Principal that the agreement/authorization is still in effect must be submitted. For locally manufactured medical devices with exclusive distributors, the agreement should be duly notarized. For locally manufactured medical devices with a toll manufacturer, the agreement between the trader and the manufacturer should be duly notarized.	Principal/Source/Manufacturer
For Imported Medical Devices - 1 copy of government-issued certificate attesting to the status of the Manufacturer with regard to the competence and reliability of the personnel and facilities, a Quality Systems Certificate of approval, or a compliance certificate for ISO 13485. Must be valid. Copy of the certificate shall be accompanied by a notarized declaration from the legal manufacturer or product owner attesting that the certificate is true and correct. For products that are manufactured in multiple sites or toll manufacturers, identify or highlight the product source. The product being applied must be indicated in the scope. For locally manufactured products, submit the valid LTO of the manufacturer.	Principal/Source/Manufacturer
For imported medical devices, 1 copy of the product approval issued by the NRA of any ASEAN-member country under the AMDD-CSDT requirements. ***** Must be valid. The copy of the certificate shall be accompanied by a notarized declaration from the legal manufacturer or product owner attesting that the certificate is true and correct.	Principal/Source/Manufacturer
Clear colored picture of the actual commercial product sample of the device for all sides without its packaging, for all the codes included in the application. An actual representative sample or commercial presentation can be required by the CDRRHR for verification purposes. Pictures should not be pixelated when the view is increased in size.	Applicant or Principal/Source/Manufacturer
Technical Requirements	

Executive Summary. The executive summary shall include the following information: an overview, e.g., introductory descriptive information on the medical device, the intended uses and indications for use of the medical device, any novel features and a synopsis of the content of the CSDT; the commercial marketing history; the list of regulatory approvals or marketing clearances obtained; the status of any pending request for market clearance; and the important safety/performance related information.	Applicant or Principal/Source/Manufacturer
Relevant essential principles and method/s used to demonstrate conformity. Must be completely filled-up.	Principal/Source/Manufacturer
Device description with the following information: Intended use- this refers to the use for which the medical device is intended, for which it is suited according to the data supplied by the product owner in the instructions as well as the functional capability of the medical device. If the product is part of the system, the specific use of the product as part of the system should be indicated and not the intended use of the system. Indications of use- this is a general description of the disease or condition that the medical device will diagnose, treat, prevent, cure or mitigate and includes a description of the target patient population for which the medical device is intended. Instruction for use- this are all necessary information from the product owner including the procedures, methods, frequency, duration, quantity and preparation to be followed for sale use of the medical device, instructions needed to use the medical device in a safe manner shall, to the extent possible, be included on the medical device itself and/or its packaging by other formats/forms. This is the detailed instruction for use for the users of the medical device. The instruction should be clear enough to guide its users. Contraindications- This is a general description of the disease or condition and the patient population for which the medical device should not be used for the purpose of diagnosing, treating, curing or mitigating. Contraindications are conditions under which the medical device should not be used because the risk of use clearly outweighs any possible benefit. Warnings-This is the specific hazard alert information that a user needs to know before using the medical device. Precautions-This alerts the user to exercise special care necessary for the safe and effective use of the medical device. They may include actions to be taken to avoid effects on patients/users that may not be potentially life	Principal/Source/Manufacturer

threatening or result in serious injury, but about which the user should be aware. Precautions may also alert the user to adverse effects on the medical device of use or misuse and the care necessary to avoid such effects. Potential adverse effects- These are potential undesirable and serious outcomes (death, injury, or serious adverse events) to the patient/user, or side effects from the use of the medical device, under normal conditions. Alternative therapy (practices and procedures) (if applicable) - This is a description of any alternative practices or procedures for diagnosing, treating, curing or mitigating the disease or condition for which the medical device is intended. Raw Materials or formulation. A description of the materials or formulation of the device and their physical properties to the extent necessary to demonstrate conformity with the relevant Essential Principles. The information shall include complete chemical, biological and physical characterization of the materials of the device. Should have a List of all raw materials used as a component of the product (specify for which product part or component the raw material is used). Must include quantity (for solutions) and technical specifications or detailed information on physical and chemical properties of each component. If the device contains PVC, identify the PVC plasticizer used. For kits/sets: submit the raw materials used with specifications of all components in the kit/set. For machines/equipment: The list of raw materials is ONLY required for the machine parts/accessories that: 1) will have a direct contact with the patient; and/or 2) will serve as a channel/conduit for medical gases during infusion (i.e. ventilators) - parts that come in direct contact with medical gases for infusion. Other Relevant Specifications to include the following: j.1 The functional characteristics and technical performance specifications of the device including, as relevant: accuracy, sensitivity, specificity of measuring and diagnostic medical devices, reliability, and other factors j.2 Other specifications including chemical, physical, electrical, mechanical, biological, software, sterility, stability, storage and transport, and packaging. May submit Certificate of Analysis or Test Certificate with finished product specification. For Stability, submit functionality and packaging/integrity test study of the product duly signed by the person who conducted the studies to justify the claimed expiration date. For accelerated study, submit computation to justify the storage conditions used. If no expiration, submit justification from the manufacturer why the device has no expiration. Submit in-use stability study, as applicable. (e.g. contact lens solution, disinfectant) Identify the product's storage condition.	

For products with special storage conditions, submit transport stability study. For packaging, clarify the type of packaging used. i.e. blister pack, carton box, etc. For medical devices with animal tissue origin, submit Certificate of Compliance with ISO 22442 - Medical devices utilizing animal tissues and their derivatives issued by Government Authority or notified body. Other Descriptive Information to demonstrate conformity with the relevant Essential Principles (e.g. biocompatibility category for the finished medical device)	
Summary of Design Verification and Validation Documents: The validation documents shall consist of the following: Declaration/Certificates of Conformity to the product standards issued by the manufacturer Summaries or reports of tests and evaluation based on other standards, manufacturer methods and tests, or alternative ways of demonstrating compliance, such as a listing of and conclusions drawn from published reports that concern the safety and performance of aspects of the medical device with reference to the Essential Principles; Data summaries or tests reports and evaluations covering the following appropriate test reports, whichever is applicable: Engineering test, including software validation studies, if applicable Laboratory test Biocompatibility test/biological evaluation Animal Test Simulated Use Clinical evidence Implantable devices Newly introduced devices Devices incorporating new materials coming into contact with the patient Existing materials applied in a body part not previously exposed to that material, and for which no prior chemical experience exists An existing device that is modified and the modification might affect the safety and effectiveness All other medical devices under Class D	Principal/Source/Manufacturer

Clinical evidence of the effectiveness may comprise of medical device-related investigations conducted domestically or other countries, or it may be derived from relevant publications in peer-reviewed scientific literature. The documented evidence submitted should include the objectives, methodology and results presented in context, clearly and meaningfully. The conclusions on the outcome of the clinical studies should be preceded by a discussion in context with the published literature. For Class D medical devices: A bibliography of all published reports dealing with the use, safety, and effectiveness of the device. Submit the most recent published reports for the medical device	
Clear and complete colored pictures of label from all sides of the packaging (loose label or artworks of all layers of packaging): Immediate label, secondary packaging, box label and package insert/brochure, whichever is applicable. For any additional product claims on the label, submit studies or tests supporting the claims. For imported products, if the brand name is the product's local brand, declaration from the manufacturer allowing use of the brand name and IPO approval of the said brand name. For local manufactured products, IPO approval of the said brand name If the CE marking is reflected on the label, submit a valid certificate supporting the placement of the CE mark. Pictures and text of the label should be clear and will not be pixelated when the view is increase in size Lot No., Batch No., Serial No., whichever is applicable should be reflected Expiration date, reference codes/sizes/variants/model whichever is applicable should be reflected Storage condition, sterilization method should be reflected if applicable Importer and distributor's name and address should be reflected in the label of the product together with the Registration Number. Suggested Retail Price (SRP) in Philippine peso. The above requirements shall be superseded upon the approval of Administrative Order for the labeling requirements for medical devices.	Applicant or Principal/Source/Manufacturer
. Risk assessment which consists of risk analysis, evaluation and reduction measures. Identify the risk Submit Failure Mode Effect Analysis (FMEA) / Risk Benefit Analysis Evaluation of the effectiveness of control measures	Principal/Source/Manufacturer
. Physical Manufacturer information:	Principal/Source/Manufacturer

Manufacturing process, including quality assurance measures. This should include the manufacturing methods and procedures, manufacturing environment or conditions, facilities and controls. The information may be presented in the form of a process flow chart showing an overview of production, controls, assembly, final product testing, and packaging of finished medical device. A brief summary of the sterilization method should be included. Include sterilization standard parameters, sterilization procedures, validation protocol and results of latest sterilization revalidation. If the sterilization of the device is contracted out, submit copy of valid ISO Certificate of the contracted sterilizing company. For non-sterile devices: a) submit Non-sterile declaration from the manufacturer; b) If the device is required to be sterilized prior to use, submit recommended sterilization guidelines from the manufacturer.	
Documentary requirements must be arranged according to the CSDT format. Submit an electronic/scanned copy (in PDF searchable format of at least 150 dpi) The soft copy should be arranged according to the checklist of requirements. The file name should consist of the name of the requirement. The electronic copy should be contained either in one single continuous file per requirement or single continuous file for all requirements. Provide table of contents with page number	

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME**	PERSON RESPONSIBLE
Client sends an email containing the PDF file of their application to cdrrhr-productregistration@fda.gov.ph following the correct schedule of application.	1 Receiving officer sends an acknowledgment email to the client and decks the application to the evaluator for pre-assessment.	None		CDRRHR officer
	2 Pre-assessment and issuance of Order of Payment or Denial Letter.	None		CDRRHR Evaluator
The applicant company receives the Order of Payment and pays the assessed fee through FDAC Cashier or any other means prescribed by FDA. (e.g. BANCNET, LANDBANK ONCOLL).	. The FDA receives the payment from the applicant company for posting	PHP7,575.00	Timeline starts after posting of payment	FDA Cashier

The Order of Payment will only be valid for 3 working days.				
The applicant company receives the official receipt and sends the proof of payment to cdrrhr-productregistration@fda.gov.ph through email.	1	CDRRHR assigns the application to evaluator	None	1 working day	CDRRHR Administrative Staff
	2	The technical evaluator reviews the application. Recommends approval or disapproval.	None	8 working days***	Technical Evaluator
	3	Quality Assurance - Checking of recommendation of the Supervisor	None	3 working days	LRD Chief
	4	Drafting and finalization of CPR.	None	2 working days	Technical Evaluator
	5	Final Approval/Disapproval and E-Signature	None	2 working days	CDRRHR Director
	6	Assigning of number and printing of CMDR. Scanning, barcoding, and transmitting of CMDR to the Records Section.	None	3 working days	CDRRHR Administrative Staff
	7	Queuing and endorsement to the FDA Releasing Section	None	1 working day	AFS Records Officer/ Administrative Officer
		TOTAL:	PHP7,575.00	20 working days****	

*Refer to the FDA Advisory No. 2021-3084 – Abridged Processing of Applications for Registration/Notification of Medical Devices Approved by the Regulatory Authority of any ASEAN Member Country.

**Day 1 commences upon the receipt of the proof of payment / posting of payment.
***Timeline provided is for applications that are complete and correct with no Notice of Deficiencies issued.
****Service is covered under Republic Act No. 3720 Section 21 as amended by Executive Order No. 175 Section 13.
*****FDA Circular No. 2022-008: Abridged Processing of Application for Registration of Medical Devices Approved by the National Regulatory Authority of Any ASEAN Member Country

14.ISSUANCE OF CERTIFICATE OF MEDICAL DEVICE REGISTRATION (CMDR) FOR CLASS C AND D (INITIAL APPLICATION)

The application for authorization issued for medical devices that fall under Class C or D.

Center/Office/Division	:	CDRRHR-LRD
Classification	:	Highly Technical
Type of Transaction	:	G2B - Government-to-Businesses
Who May Avail	:	Medical Device Manufacturers/Distributors (Importer/Exporter/Wholesaler)/Trader
Fees to be Paid	:	Php7,500.00 + 1% LRF for initial with 5-year validity (Php. 7,575.00) per product

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
Notarized Application Form Must be completely and correctly filled-up and signed Must use the latest form prescribed by the CDRRHR for the type of application Must submit one application form with attachment reflecting all the product codes being applied. Furthermore, the grouping of medical device family should be clearly specified. Only one condition should be considered in the multiple CPR application. Must be unedited, non-tampered; and must reflect the correct brand name, medical device name, and device risk-classification.	Applicant. Form may be downloaded from the FDA website.
1 Copy of Notarized Agreement / Letter of Authorization. Must be valid; For imported medical devices, with notarized declaration from the legal manufacturer or product owner attesting that the authorization / agreement is true and correct. For imported medical devices but the agreements are signed in the Philippines, it must be notarized locally, with passport ID page and record of arrival and departure of the principal to and from the Philippines of the signatory/ies, and must be signed by both parties. For open-dated agreements/authorizations, if the certificate is beyond the 5-year period from the document's issuance, a re-issued agreement/authorization or a notarized attestation by the Principal that the agreement/authorization is still in effect must be submitted. For locally manufactured medical devices with exclusive distributors, the agreement should be duly notarized.	Principal/Source/Manufacturer

For locally manufactured medical devices with a toll manufacturer, the agreement between the trader and the manufacturer should be duly notarized.	
For Imported Medical Devices - 1 copy of government-issued certificate attesting to the status of the Manufacturer with regard to the competence and reliability of the personnel and facilities, a Quality Systems Certificate of approval, or a compliance certificate for ISO 13485. Must be valid. Copy of the certificate shall be accompanied by a notarized declaration from the legal manufacturer or product owner attesting that the certificate is true and correct. For products that are manufactured in multiple sites or toll manufacturers, identify or highlight the product source. The product being applied must be indicated in the scope. For locally manufactured products, submit the valid LTO of the manufacturer.	Principal/Source/Manufacturer
For imported medical devices, 1 copy of Certificate of Product Registration, CE Certificate or any equivalent document attesting to the safety and effectiveness of the device issued by regulatory agency or accredited notified body in the country of origin. Must be valid. The copy of the certificate shall be accompanied by a notarized declaration from the legal manufacturer or product owner attesting that the certificate is true and correct. USA FDA 510K and PMA (Post Market Approval), Online registry from the Singapore HAS, and EC Full Quality Assurance and Design Verification Certificate	Principal/Source/Manufacturer
Clear colored picture of the actual commercial product sample of the device for all sides without its packaging, for all the codes included in the application. An actual representative sample or commercial presentation can be required by the CDRRHR for verification purposes. Pictures should not be pixelated when the view is increased in size.	Applicant or Principal/Source/Manufacturer
Technical Requirements	
Executive Summary. The executive summary shall include the following information: an overview, e.g., introductory descriptive information on the medical device, the intended uses and indications for use of the medical device, any novel features and a synopsis of the content of the CSDT; the commercial marketing history; the list of regulatory approvals or marketing clearances obtained; the status of any pending request for market clearance; and the important safety/performance related information.	Applicant or Principal/Source/Manufacturer

Relevant essential principles and method/s used to demonstrate conformity. Must be completely filled-up.	Principal/Source/Manufacturer
Device description with the following information: Intended use- this refers to the use for which the medical device is intended, for which it is suited according to the data supplied by the product owner in the instructions as well as the functional capability of the medical device. If the product is part of the system, the specific use of the product as part of the system should be indicated and not the intended use of the system. Indications of use- this is a general description of the disease or condition that the medical device will diagnose, treat, prevent, cure or mitigate and includes a description of the target patient population for which the medical device is intended. Instruction for use- this are all necessary information from the product owner including the procedures, methods, frequency, duration, quantity and preparation to be followed for sale use of the medical device, instructions needed to use the medical device in a safe manner shall, to the extent possible, be included on the medical device itself and/or its packaging by other formats/forms. This is the detailed instruction for use for the users of the medical device. The instruction should be clear enough to guide its users. Contraindications- This is a general description of the disease or condition and the patient population for which the medical device should not be used for the purpose of diagnosing, treating, curing or mitigating. Contraindications are conditions under which the medical device should not be used because the risk of use clearly outweighs any possible benefit. Warnings-This is the specific hazard alert information that a user needs to know before using the medical device. Precautions-This alerts the user to exercise special care necessary for the safe and effective use of the medical device. They may include actions to be taken to avoid effects on patients/users that may not be potentially life threatening or result in serious injury, but about which the user should be aware. Precautions may also alert the user to adverse effects on the medical device of use or misuse and the care necessary to avoid such effects. Potential adverse effects- These are potential undesirable and serious outcomes (death, injury, or serious adverse events) to the patient/user, or side effects from the use of the medical device, under normal conditions.	Principal/Source/Manufacturer

Alternative therapy (practices and procedures) (if applicable) - This is a description of any alternative practices or procedures for diagnosing, treating, curing or mitigating the disease or condition for which the medical device is intended. Raw Materials or formulation. A description of the materials or formulation of the device and their physical properties to the extent necessary to demonstrate conformity with the relevant Essential Principles. The information shall include complete chemical, biological and physical characterization of the materials of the device. Should have a List of all raw materials used as a component of the product (specify for which product part or component the raw material is used). Must include quantity (for solutions) and technical specifications or detailed information on physical and chemical properties of each component. If the device contains PVC, identify the PVC plasticizer used. For kits/sets: submit the raw materials used with specifications of all components in the kit/set. For machines/equipment: The list of raw materials is ONLY required for the machine parts/accessories that: 1) will have a direct contact with the patient; and/or 2) will serve as a channel/conduit for medical gases during infusion (i.e. ventilators) - parts that come in direct contact with medical gases for infusion. Other Relevant Specifications to include the following: j.1 The functional characteristics and technical performance specifications of the device including, as relevant: accuracy, sensitivity, specificity of measuring and diagnostic medical devices, reliability, and other factors j.2 Other specifications including chemical, physical, electrical, mechanical, biological, software, sterility, stability, storage and transport, and packaging. May submit Certificate of Analysis or Test Certificate with finished product specification. For Stability, submit functionality and packaging/integrity test study of the product duly signed by the person who conducted the studies to justify the claimed expiration date. For accelerated study, submit computation to justify the storage conditions used. If no expiration, submit justification from the manufacturer why the device has no expiration. Submit in-use stability study, as applicable. (e.g. contact lens solution, disinfectant) Identify the product's storage condition. For products with special storage conditions, submit transport stability study. For packaging, clarify the type of packaging used. i.e. blister pack, carton box, etc. For medical devices with animal tissue origin, submit Certificate of Compliance with ISO 22442 - Medical devices utilizing animal tissues and their derivatives issued by Government Authority or notified body.	

Other Descriptive Information to demonstrate conformity with the relevant Essential Principles (e.g. biocompatibility category for the finished medical device)	
Summary of Design Verification and Validation Documents: The validation documents shall consist of the following: Declaration/Certificates of Conformity to the product standards issued by the manufacturer Summaries or reports of tests and evaluation based on other standards, manufacturer methods and tests, or alternative ways of demonstrating compliance, such as a listing of and conclusions drawn from published reports that concern the safety and performance of aspects of the medical device with reference to the Essential Principles; Data summaries or tests reports and evaluations covering the following appropriate test reports, whichever is applicable: Engineering test, including software validation studies, if applicable Laboratory test Biocompatibility test/biological evaluation Animal Test Simulated Use Clinical evidence: Implantable devices Newly introduced devices Devices incorporating new materials coming into contact with the patient Existing materials applied in a body part not previously exposed to that material, and for which no prior chemical experience exists An existing device that is modified and the modification might affect the safety and effectiveness All other medical devices under Class D	Principal/Source/Manufacturer

Clinical evidence of the effectiveness may comprise of medical device-related investigations conducted domestically or other countries, or it may be derived from relevant publications in peer-reviewed scientific literature. The documented evidence submitted should include the objectives, methodology and results presented in context, clearly and meaningfully. The conclusions on the outcome of the clinical studies should be preceded by a discussion in context with the published literature. For Class D medical devices: A bibliography of all published reports dealing with the use, safety, and effectiveness of the device. Submit the most recent published reports for the medical device	
Clear and complete colored pictures of label from all sides of the packaging (loose label or artworks of all layers of packaging): Immediate label, secondary packaging, box label and package insert/brochure, whichever is applicable. For any additional product claims on the label, submit studies or tests supporting the claims. For imported products, if the brand name is the product's local brand, declaration from the manufacturer allowing use of the brand name and IPO approval of the said brand name. For local manufactured products, IPO approval of the said brand name If the CE marking is reflected on the label, submit a valid certificate supporting the placement of the CE mark. Pictures and text of the label should be clear and will not be pixelated when the view is increase in size Lot No., Batch No., Serial No., whichever is applicable should be reflected Expiration date, reference codes/sizes/variants/model whichever is applicable should be reflected Storage condition, sterilization method should be reflected if applicable Importer and distributor's name and address should be reflected in the label of the product together with the Registration Number. Suggested Retail Price (SRP) in Philippine peso. The above requirements shall be superseded upon the approval of Administrative Order for the labeling requirements for medical devices.	Applicant or Principal/Source/Manufacturer
. Risk assessment which consists of risk analysis, evaluation and reduction measures. Identify the risk Submit Failure Mode Effect Analysis (FMEA) / Risk Benefit Analysis Evaluation of the effectiveness of control measures	Principal/Source/Manufacturer

. Physical Manufacturer information: Manufacturing process, including quality assurance measures. This should include the manufacturing methods and procedures, manufacturing environment or conditions, facilities and controls. The information may be presented in the form of a process flow chart showing an overview of production, controls, assembly, final product testing, and packaging of finished medical device. A brief summary of the sterilization method should be included. Include sterilization standard parameters, sterilization procedures, validation protocol and results of latest sterilization revalidation. If the sterilization of the device is contracted out, submit copy of valid ISO Certificate of the contracted sterilizing company. For non-sterile devices: a) submit Non-sterile declaration from the manufacturer; b) If the device is required to be sterilized prior to use, submit recommended sterilization guidelines from the manufacturer.	Principal/Source/Manufacturer
Documentary requirements must be arranged according to the CSDT format. Submit an electronic/scanned copy (in PDF searchable format of at least 150 dpi) The soft copy should be arranged according to the checklist of requirements. The file name should consist of the name of the requirement. The electronic copy should be contained either in one single continuous file per requirement or single continuous file for all requirements. Provide table of contents with page number	

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME*	PERSON RESPONSIBLE
1. Client sends an email containing the PDF file of their application to cdrrhr-productregistration@fda.gov.ph following the correct schedule of application.	1.1 Receiving officer sends an acknowledgment email to the client and decks the application to the evaluator for pre-assessment.	None		CDRRHR officer
	1.2 Pre-assessment and issuance of Order of Payment or Denial Letter.	None		CDRRHR Evaluator

2. The applicant company receives the Order of Payment and pays the assessed fee through FDAC Cashier or any other means prescribed by FDA. (e.g. BANCNET, LANDBANK ONCOLL). The Order of Payment will only be valid for 3 working days.	2 FDA receives the payment from the applicant company for posting	PHP7,575.00	Timeline starts after posting of payment	FDA Cashier
3 The applicant company receives the official receipt and sends the proof of payment to cdrrhr-productregistration@fda.gov.ph through email.	3.1 CDRRHR assigns the application to evaluator.	None	2 working days	CDRRHR Administrative Staff
	3.2 The technical evaluator reviews the application. Recommends approval or disapproval.	None	83 working days**	Technical Evaluator
	3.3 Quality Assurance - Checking of recommendation of the Supervisor	None	10 working days	LRD Chief
	3.4 Drafting and finalization of CPR.	None	3 working days	Technical Evaluator
	3.5 Final Approval/Disapproval and E- Signature	None	5 working days	CDRRHR Director
	3.6 Assigning of number and printing of CMDR. Scanning, barcoding, and transmitting of CMDR to the Records Section.	None	6 working days	CDRRHR Administrative Staff

	3.7 Queuing and endorsement to FDA Releasing Section	None	1 working day	AFS Records Officer/ Administrative Officer
	TOTAL	PHP7,575.00	110 working days***	

*Day 1 commences upon the receipt of the proof of payment / posting of payment.

**Timeline provided is for applications that are complete and correct with no Notice of Deficiencies issued.

***Service is covered under Republic Act No. 3720 Section 21 as amended by Executive Order No. 175 Section 13.

15.ISSUANCE OF CERTIFICATE OF PRODUCT REGISTRATION (CPR) FOR EQUIPMENT/DEVICES USED TO TREAT SHARPS, PATHOLOGICAL AND INFECTIOUS WASTES (INITIAL APPLICATION)

The application for authorization issued for equipment/devices used to treat sharps, pathological and infectious wastes.

Center/Office/Division	:	CDRRHR-LRD
Classification	:	Highly Technical
Type of Transaction	:	G2B - Government-to-Businesses
Who May Avail	:	Medical Device Manufacturers/Distributors (Importer/Exporter/Wholesaler)/Trader
Fees to be Paid	:	Manufacturers/Distributors/TSD Facility A) Below Php 1,000,000.00: 5,000 + 1% LRF = Php5,050.00 B) Php 1,000,000 – Php 5,000,000: 8,000 + 1% LRF = Php8,080.00 C) Above Php 5,000,000: 10,000 + 1% LRF = Php10,100.00 Healthcare Waste Generators: 3,000 + 1% LRF = Php3,030.00

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
Properly and completely filled-up application form Must be signed by the company representative and dated Location of Installation shall be filled-up since the equipment will be inspected and tested for performance evaluation.	Applicant. Form may be downloaded from the FDA website.

Copy of SEC Articles of Incorporation or DTI Certificate of Business Registration The activity of manufacturing, importing or distributing the equipment should be reflected in the Articles of Incorporation The DTI Certificate of Business Registration must be valid.	Applicant
Technology Approval from DOST-ITDI for new technologies	Applicant
Technical Report:	
4.1. Company profile;	Applicant
4.2. Characteristics and Sources of generated waste;	Applicant
4.3. Detailed description of treatment equipment to be tested including manufacturer's instructions and technical specifications;	Applicant
4.4. Operating procedures and conditions including as applicable treatment time, pressure, temperature, chemical concentration, doses, feed rates and waste load composition;	Applicant
4.5. Storage, handling and volume capacity;	Applicant
4.6. Applicable emission controls for suspected emissions;	Applicant
4.7. Potential hazards/toxicities of waste residues;	Applicant
4.8. Energy efficiency	Applicant
4.9. Occupational safety and health assurance.	Applicant
Copy of Operation Manual	Applicant
Layout / Plans	Applicant
6.1. Location of installation;	Applicant
6.2. Design / Drawing or picture of the device / equipment applied for;	Applicant
Supplementary requirements for equipment / devices used for chemical disinfection:	Applicant
7.1. Material Safety Data Sheet (MSDS) of the chemicals to be used for disinfection	Applicant
7.2. The chemical to be used should be registered with the DENR-EMB or must be compliant with the WHO guidelines for hazardous wastes.	Applicant

For healthcare waste generators (e.g. hospitals) and Treatment, Storage and Disposal (TSD) Facilities, the Environmental Compliance Certificate (ECC) issued by the Environmental Management Bureau-Department of Environment and Natural Resources (EMB-DENR) and the License to Operate issued by the Department of Health shall be submitted together with the above documentary requirements. - License to Operate should be valid	Applicant
Copy of valid License to Operate (LTO)	Applicant
Notes: . This office shall not accept applications with incomplete requirements. . All documents should be submitted in electronic copy format. . All information contained in this application form will be held strictly confidential.	
*Submission schedule is every Friday from 8:00 AM to 5:00 PM. This schedule applies to working days only and excludes national and declared non-working days. In the event of a holiday/non-working day, then the regular schedule shall be followed on the next working and scheduled submission day.	

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME*	PERSON RESPONSIBLE
1. Client sends an email containing the PDF of their application to cdrrhr-productregistration@fda.gov.ph following the correct schedule.	1.1 Receiving officer sends an acknowledgment email to the client and decks the application to the evaluator for pre-assessment.	None	Timeline starts after posting of payment	CDRRHR Officer
	1.2 Pre-assessment and issuance of Order of Payment or Denial Letter. (10 working days)			Technical Evaluator

2 The applicant company receives the Order of Payment and pays the assessed fee through FDAC Cashier or any other means prescribed by FDA. (e.g. BANCNET, LANDBANK ONCOLL). The Order of Payment will only be valid for 3 working days.	2. FDA receives the payment from the applicant company for posting.	Below Php 1,000,000.00: 5,000 + 1% LRF = Php5,050.00 Php 1,000,000 – Php 5,000,000: 8,000 + 1% LRF = Php8,080.00 Above Php 5,000,000: 10,000 + 1% LRF = Php10,100.00 Healthcare Waste Generators: 3,000 + 1% LRF = Php3,030.00		FDA Cashier
3 The applicant company receives the official receipt and sends the proof of payment to cdrrhr-productregistration@fda.gov.ph through email	3.1 The CDRRHR will assign the application to evaluator	None	2 working days	CDRRHR Admin Staff
.	3.2 Technical evaluation of application. Issuance of a Notice of Deficiencies or endorsement.	None	20 working days	Technical Evaluator

4. Client complies with the Notice of Deficiencies *Clients are given 30 days to comply with the NOD. Non-compliance would mean disapproval of the application.	4.1 Evaluator reviews compliance documents. Once fully complied, endorsed to NRL for Performance Evaluation.	None	11 working days	Technical Evaluator
	Performance Testing	c/o NRL	Timeline depends on the NRL Procedure	c/o EAMC-NRL
	4.2 Review of Performance Evaluation report	None	5 working days	Technical Evaluator
	4.3 Quality Assurance - Checking of recommendation of the Supervisor	None	5 working days	LRD Chief
	4.4 Drafting and finalization of CPR.	None	2 working days	Administrative Officer
	4.5 Final Approval/Disapproval and signature of the Director	None	2 working days	CDRRHR Director
	4.6 Assigning of number and printing of certificate. Transmital to Record Section	None	1 working day	CDRRHR Administrative Staff
	4.7 Scanning and Barcoding of CPR. Queuing and Endorsement to Releasing Section.	None	2 working days	AFS Records Officer / Administrative Officer
	TOTAL	Php5,050.00/ Php8,080.00/	50 working days**	

		Php10,100.00/ Php3,030.00		

*Day 1 commences upon the receipt of the proof of payment / posting of payment.

**Service is covered under Republic Act No. 3720 Section 21 as amended by Executive Order No. 175 Section 13.

16.ISSUANCE OF CERTIFICATE OF PRODUCT REGISTRATION (CPR) FOR IN-VITRO DIAGNOSTIC DEVICES/REAGENTS (IVD) (INITIAL APPLICATION)

The application for authorization issued for In Vitro Diagnostic Devices or Reagents.

Center/Office/Division	:	CDRRHR-LRD
Classification	:	Highly technical
Type of Transaction	:	G2B - Government-to-Businesses
Who May Avail	:	Medical Device Manufacturers/Distributors (Importer/Exporter/Wholesaler)/Trader
Fees to be Paid	:	Php1,500.00 + 1% LRF for initial with 1-year validity* Additional Php1,000.00 + 1% LRF if the product is for the detection of HCG (pregnancy test kit), which requires performance evaluation testing *Cost does not include the performance evaluation test; cost of testing depends on the corresponding National Reference Laboratory (NRL).

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
1. Table of Contents with correct page number	Applicant
Notarized Application Form Must be completely filled-up; Model / Reference Number / Sizes / Codes must be properly identified; Refrain from indicating the Brand name (if applicable) on the Name of the product and vice versa For kits/sets, identify the complete contents/inclusions on the space provided for device name; For multiple models / reference number / size / codes, an annex page may be attached; For multiple models / reference number / size / codes; a Word copy must be submitted Should be signed by the proper authority as indicated on the form; Re-using forms is not acceptable since this is a legal document.	Applicant Form may be downloaded from the FDA website.

License to Operate (LTO) as a Medical Device Distributor (Importer/ Exporter/ Wholesaler)/ Local Manufacturer/Trader. Shall be valid The principal shall be reflected on the list of sources.	Applicant
Government Certificate of Clearance and Free Sale/Registration approval from the country of origin issued by the Health Authority Shall be valid Shall be authenticated/apostilled by the territorial Philippine Consulate for Imported Product. For products with a trade name or reference code that differs per country, submit declaration or clarification from the manufacturer/principal. The product shall be stated on the list.	Principal/Source/ Manufacturer
For Imported Products - government issued certificate attesting to the status of the Manufacturer with regard to the competence and reliability of the personnel and facilities, a Quality Systems Certificate of approval, or a compliance certificate for ISO 13485. Shall be valid Shall be authenticated/apostilled by the territorial Philippine Consulate For products that are manufactured in multiple sites or toll manufacturers, identify or highlight where the product will be sourced from. The product being applied must be indicated in the scope. For locally manufactured products, valid LTO of the manufacturer	Principal/Source/ Manufacturer

Foreign Agency Agreement / Letter of Authorization. Shall be valid. Shall be authenticated/apostilled by the territorial Philippine Consulate. The product being applied must be indicated. For imported medical devices but the agreements are signed in the Philippines, it must be notarized locally, with passport ID page and record of arrival and departure of the principal to and from the Philippines of the signatory/ies, and must be signed by both parties. For open-dated agreements/authorizations, if the certificate is beyond the 5-year period, a re-issued agreement/authorization must be submitted or a notarized attestation by the Principal that the agreement/authorization is still in effect. For locally manufactured medical devices with exclusive distributors, the agreement should be duly notarized. For locally manufactured medical devices with toll manufacturer, agreement between the trader and the manufacturer should be duly notarized.	Applicant or Principal/Source/Manufacturer
Technical Requirements	
Intended use and Directions for Use which includes the following Intended use - this refers to the use for which the medical device is intended, for which it is suited according to the data supplied by the product owner in the instructions as well as the functional capability of the medical device. If the product is part of the system, the specific use of the product as part of the system should be indicated and not the intended use of the system. Indications of use - this is a general description of the disease or condition that the medical device will diagnose, treat, prevent, cure or mitigate and includes a description of the target patient population for which the medical device is intended. Instruction for use - these are all necessary information from the product owner including the procedures, methods, frequency, duration, quantity and preparation to be followed for sale use of the	Principal/Source/Manufacturer

medical device, instructions needed to use the medical device in a safe manner shall, to the extent possible, be included on the medical device itself and/or its packaging by other formats/forms. This is the detailed instruction for use for the users of the medical device. The instruction should be clear enough to guide its users. Contraindications - This is a general description of the disease or condition and the patient population for which the medical device should not be used for the purpose of diagnosing, treating, curing or mitigating. Contraindications are conditions under which the medical device should not be used because the risk of use clearly outweighs any possible benefit. Warnings - This is the specific hazard alert information that a user needs to know before using the medical device. Precautions - This alerts the user to exercise special care necessary for the safe and effective use of the medical device. They may include actions to be taken to avoid effects on patients/users that may not be potentially life threatening or result in serious injury, but about which the user should be aware. Precautions may also alert the user to adverse effects on the medical device of use or misuse and the care necessary to avoid such effects. Potential adverse effects- These are potential undesirable and serious outcomes (death, injury, or serious adverse events) to the patient/user, or side effects from the use of the medical device, under normal conditions. Intended purpose, including the following information: Type of analyte or measure of the assay. Whether the test is quantitative or qualitative. Role of the test in the clinical use e.g. screening, diagnostic or detection, aid to diagnostic, monitoring. Disease or condition that the test is intended for. Type of specimen to be used e.g. serum, plasma etc. The intended users (e.g. Self-testing by lay person, near- patient by trained personnel or professionals). Assay type e.g. immunoassay, chemistry, cytochemistry, image analysis, immunohistochemistry. The specific name of the instrument required for the assay, if any.	

Test principle. Specimen type. Conditions for collection, handling, storage and preparation of the specimen. Reagent description and any limitation (e.g. use with a dedicated instrument only). Metrological traceability of values assigned to calibrators and trueness-control materials, including identification of applicable reference materials and/or reference measurement procedures of higher order. Assay procedure including calculations and interpretation of results. Information on interfering substances that may affect the performance of the assay. Performance characteristics (summarized analytical and diagnostic sensitivity, specificity, reproducibility, etc.) Reference intervals. Study design (population studies, N, type of sample, matrix, dilution, target concentrations, etc.).	
List of all raw materials used as components of the reagents/test kit Product part or component where the raw material is used shall be specified Must include quantity (for solutions) and technical specifications or detailed information on physical and chemical properties of each component. If the product contains PVC, identify the PVC plasticizer used. For kits/sets submit all raw materials and specifications used.	Principal/Source/Manufacturer
Technical specifications of the Finished Product	Principal/Source/ Manufacturer

. Analytical and clinical performance studies to support IVD performance claims: Specimen type (suitability, collection, storage and transport stability) Equivalence between specimen types Analytical performance characteristics accuracy trueness and bias precision (repeatability and reproducibility) Analytical sensitivity (limit of detection, detection of variants) Analytical specificity (interference and cross-reactivity) Measuring range of the assay Validation of assay cut-off Validation of assay reading time Complete performance study to justify all the claims on the package insert	Principal/Source/Manufacturer
. Brief description of the manufacturing procedure/flowchart which shall include the ff: methods used in the facility controls in the manufacture processing packaging process flowchart showing an overview of production	Principal/Source/Manufacturer
. Risk Analysis to include the results Identify the risk Submit Failure Mode Effect Analysis	Principal/Source/Manufacturer
. Stability test data and results which shall include: shelf life study in-use stability study shipping stability studies to justify claimed shelf life Note: - Shall be performed on at least three (3) different product lots.	Principal/Source/Manufacturer

- For accelerated study, indicate storage conditions, duration of study and computation to justify the storage condition used.	
. Labeling materials Immediate label secondary packaging box label package insert/brochure. shall include blood sample collection and handling performance study results and summary cross reactivity and list of potential interfering substances (if applicable) warnings and precautions information of the manufacturer revision number	Principal/Source/ Manufacturer
. For pregnancy test kit, 15 samples of the same lot with at least nine (9) months expiration date. NOTE: For other IVD applications, samples will be submitted directly to the respective NRLs. Number of samples required will depend on the requirement of each NRL. Take note that the labeling materials for all the samples should be complete and the same.	Applicant
16. Evidence of registration fee/payment (charge slip/official receipt)	FDA Cashier
All documents shall be submitted in English language. Documents submitted in any other foreign language not accompanied by English Translation shall be disapproved. Submit an electronic/scanned copy (in PDF searchable format of at least 150dpi). The soft copy shall be arranged according to the checklist of requirements. The file name shall consist of the name of the requirement. The electronic copy shall be contained either in one single continuous file per requirement or single continuous file for all requirements. Bring hard copy of the assessment slip.	

Submission schedule will be generated by the FDA and sent thru email to client	

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME*	PERSON RESPONSIBLE
1. Client sends and email containing the PDF file of their application to cdrrhr-productregistration@fda.gov.ph following the correct schedule of application.	1.1 Receiving officer sends an acknowledgment email to the client and decks the application to the evaluator for pre-assessment.	None		CDRRHR Officer
	1.2 Pre-assessment and issuance of Order of Payment or Denial Letter.	None		Technical Evaluator
2. The applicant company receives the Order of Payment and pays the assessed fee through FDAC Cashier or any other means prescribed by FDA. (e.g. BANCNET, LANDBANK ONCOLL) The Order of Payment will only be valid for 3 working days.	2 FDA receives the payment from the applicant company for posting.	Php1,500.00 + 1% LRF for initial with 1-year validity* Additional Php1,000.00 + 1% LRF if the product is for the detection of HCG (pregnancy test) which requires performance evaluation testing.	Timeline starts after posting of payment	FDA Cashier

		Cost does not include the performance evaluation test; cost of testing depends on the corresponding National Reference Laboratory (NRL)		
3. The applicant company receives the official receipt and sends the proof of payment to cdrrhr-productregistration@fda.gov.ph through email.	3.1 CDRRHR assigns the application to the evaluator.	None	1 working day	CDRRHR Admin Staff
.	3.2 The technical evaluator reviews the application. Recommends approval, disapproval, or notice of deficiency.	None	80 working days**	Technical Evaluator
.	3.3 Endorsement of the application to NRL for performance evaluation.	None	1 working day	Technical Evaluator
.	3.4 Performance Testing	c/o NRL	*Timeline depends on the NRL Procedure	c/o the National Reference Laboratory
	3.5 Review of Performance Evaluation report.	None	5 working days	Technical Evaluator
.	3.6 Quality Assurance - Checking of recommendation of the Supervisor	None	10 working days	LRD Chief

	3.7 Drafting and finalization of CPR.	None	2 working days	Technical Evaluator
.	3.8 Final Approval /Disapproval and signature of the Director	None	2 working days	CDRRHR Director
	3.9 Transmittal to the Records Section.	None	1 working day	CDRRHR Administrative Staff
	3.10 canning and barcoding of CPR. Queuing and endorsement to the FDA Releasing Section.	None	3 working days	AFS Records Officer / Admin Officer
	TOTAL	PHP1,515.00 For HCG pregnancy test kits – additional PHP1,010.00	105 working days***	

*Day 1 commences upon the receipt of the proof of payment / posting of payment.

**Timeline provided is for applications that are complete and correct with no Notice of Deficiencies issued.

***Service is covered under Republic Act No. 3720 Section 21 as amended by Executive Order No. 175 Section 13.

17.ISSUANCE OF CERTIFICATE OF REGISTRATION FOR WATER PURIFICATION DEVICES/SYSTEM (INITIAL APPLICATION)

The application for authorization issued for water purification devices or systems.

Center/Office/Division	:	CDRRHR-LRD
Classification	:	Highly Technical
Type of Transaction	:	G2B - Government-to-Businesses
Who May Avail	:	Medical Device Manufacturers/Distributors (Importer/Exporter/Wholesaler)/Trader
Fees to be Paid	:	Water Treatment Devices: Php500.00 + Php10.00 (1%) LRF per product = Php510.00 Water Treatment System: Php1,000.00 + Php10.00 (1%) LRF per product = Php1,010.00

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
Properly and completely filled-up application form Must be signed by the company representative with date when signed. Claims should only be either for safe drinking water of purified water. Claims such as alkaline, ionized, PI, oxygenated or energized are not acceptable. Latest form should be used.	Applicant. Form may be downloaded from the FDA website.
Copy of SEC Articles of Incorporation or DTI Certificate of Business Registration The activity of manufacturing, importing or distributing the device should be reflected in the Articles of Incorporation The DTI Certificate of Business Registration must be valid.	Applicant

Copy of Mayor's Permit Must be Valid Name and address in the Mayor's Permit should be the same in the application form	Applicant
4. Copy of Operation Manual - Name and model number of the device in the operation manual should be the same with the application form and label	
Layout of devices or flowchart of treatment process. - The lay out or flowchart should show every stage how the water is being treated. - Include a narrative description for every stage or step of the treatment process - Submit a clear and colored photo of the device.	Applicant
6. List of raw materials used as components of the water purification device/system. - Should have a list of the component parts with the corresponding raw material used in the device.	Applicant
Label/labelling/product insert of manufacturer's performance claim Should be clear and readable. Name of the product and model number in the label should be consistent with the name and model number in the application form and operation manual. Name and address of the manufacturer, importer and distributor should be reflected Provide provision for the registration number	Applicant
8. For special claims, data from scientific research and laboratory analysis supporting and proving the claims of the manufacturer of the product	Applicant
9. Copy of valid License to Operate (LTO)	Applicant

NOTE: Submit an electronic/scanned copy (in PDF searchable format of at least 150 dpi) The soft copy should be arranged according to the checklist of requirements. The file name should consist of the name of the requirement. The electronic copy should be contained either in one single continuous file per requirement or single continuous file for all requirements. *Submission schedule is every Friday from 8:00 AM to 5:00 PM. This schedule applies to working days only and excludes national and declared non-working days. In the event of a holiday/non-working day, then the regular schedule shall be followed on the next working and scheduled submission day.	

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
1. Client sends an email containing the PDF of their application to cdrrhr-productregistration@fda.gov.ph following the correct schedule of application.	1.1 Receiving officer sends an acknowledgment email to the client and decks the application to the evaluator for pre-assessment.	None		CDRRHR Officer
	1.2 Pre-assessment and issuance of Order of Payment or Denial Letter.	None		Technical Evaluator
2. The applicant company receives the Order of Payment and pays the assessed fee through	2.1 FDA receives the payment from the applicant company for posting.	See above table	Timeline starts after posting of payment	FDA Cashier

	FDAC Cashier or any other means prescribed by FDA. (e.g. BANCNET, LANDBANK ONCOLL). *The Order of Payment will only be valid for 3 working days		Php510.00 / Php1,010.00		
	The applicant company receives the official receipt and sends the proof of payment to cdrrhr-productregistration@fda.gov.ph through email	2.2 CDRRHR assigns the application to evaluator	None	2 Working days	CDRRHR Administrative Staff
		2.3 Technical evaluation of application. Issuance of a Notice of Deficiencies or endorsement.	None	20 working days	Technical Evaluator
3	Client complies with the Notice of Deficiencies *Clients are given 30 days to comply with the NOD. Non-compliance would mean disapproval of the application.	3.1 Evaluator reviews compliance documents.	None	10 working days	Technical Evaluator
.		3.2 Once fully complied, endorsed to NRL for Performance Evaluation	None	1 working day	Technical Evaluator

.	Performance Testing	c/o NRL	Timeline depends on the NRL procedure	c/o EAMC-NRL
	3.3 Review of Performance Evaluation report	None	5 working days	Technical Evaluator
	3.4 Quality Assurance - Checking of recommendation of the Supervisor	None	5 working days	LRD Chief
	3.5 Final Approval/Disapproval and signature of the Director	None	2 working days	CDRRHR Director
	3.6 Printing of CPR and assigning of number. Transmital to Records Section.	None	3 working days	CDRRHR Administrative Staff
.	3.7 Scanning and Barcoding of CPR. Releasing of CPR.	None	2 working days	AFS Records Officer / Administrative Officer
	TOTAL	Php510.00 / Php1,010.00	50 working days**	

*Day 1 commences upon the receipt of the proof of payment / posting of payment.

**Service is covered under Republic Act No. 3720 Section 21 as amended by Executive Order No. 175 Section 13.

18.ISSUANCE OF CLEARANCE FOR DONATION

The application for FDA clearance to facilitate the requests for, acceptance of, and distribution of all donations (medical devices) to the health sector.

Center/Office/Division	:	CDRRHR-LRD
Classification	:	Complex
Type of Transaction	:	G2G - Government-to-Government
Who May Avail	:	Medical Device Manufacturers/Distributors (Importer/Exporter/Wholesaler)/Trader
Fees to be Paid	:	None

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
Endorsement letter signed by the Director IV of the DOH-BIHC	Applicant
Folder containing the complete requirements submitted to the DOH-BIHC Letter of intent/request addressed to the BIHC Director Photocopy of the authenticated (or apostilled, if applicable) Deed of Donation by the Philippine Embassy/Consulate in the country of origin Detailed list of items to be donated, to include the following information: For devices- with detailed specifications, brand name, name of equipment, name and address of the manufacturer, expiry date if sterile Photocopy of pertinent certificates/documents, duly authenticated/apostilled from the country of origin, or notarized if locally executed, as required in Annex B (Criteria on the Acceptance of Foreign Donations) For devices- CFS, Certificate of Good Condition, if applicable	Applicant

Photocopy of the shipping documents- include packing list, bill of landing/air waybill/sea waybill, commercial invoice Letter of concurrence/acceptance from the recipient or consignee with strategic plans/development cooperation agenda of the recipient Certificate of no commercial use and given for free or Notarized Affidavit of Undertaking indicating “not for commercial distribution or sale” duly signed by the recipient/consignee Distribution/Allocation List/Plan	
NOTES: Reference: Administrative Order No. 2020-0001: Guidelines in the Importation, Facilitation and Management of Foreign Donations involving Health and Health-Related Products Clients must submit the complete requirements (AO 2020-001 – Annex C) to the Department of Health – Bureau of International Health Cooperation	

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
1. The applicant sends an email containing the PDF of their application to fdac.letters@fda.gov.ph.	1.1 FDAC Receiving Officer sends an acknowledgment email to the client.	None	1 working day	FDAC Officer
	1.2 FDAC forwards the file to CDRRHR.	None		FDAC Officer
	1.3 CDRRHR receives the file and reviews the request. Prepares the certificate or disapproval letter.	None	2 working days	CDRRHR Administrative Staff
	1.4 Quality Assurance - Checking of recommendation of the Supervisor.	None	1 working day	LRD Chief
	1.5 Final Approval/Disapproval and signature of the Director.	None	1 working day	CDRRHR Director

	1.6 Scanning and Transmittal of certificate or disapproval letter to the FDA Records Section.	None	1 working day	CDRRHR Administrative Staff
	1.7 Queuing and Endorsement to the FDA Releasing Section.	None	1 working day	AFS Records Officer / Administrative Officer
	TOTAL		7 working days**	

19.ISSUANCE OF COMPASSIONATE SPECIAL PERMIT (CSP)

The application for the restricted use of medical devices which are not yet registered or are in the process of registration in the Philippines by patients in need of immediate medical attention.

Center/Office/Division	:	CDRRHR-LRD
Classification	:	Highly technical
Type of Transaction	:	G2B - Government-to-Businesses
Who May Avail	:	Medical Device Manufacturers/Distributors (Importer/Exporter/Wholesaler)/Trader, Patient/End-User of Medical Device
Fees to be Paid	:	Php500.00 + Php10.00 LRF per permit

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
1. Letter of intent which will include a brief description of the patient, attending physician, list of specialists who will perform the administration of the medical device, the quantity of the medical device required to perform the treatment and the proposed schedule of the medical attention.	Applicant
Attending physician's profile.	Applicant
3. License to Operate as Medical Device Importer/Distributor if the product is to be supplied by a company.	Applicant
4. Letter of information regarding the importer if the medical device is to be imported by a private individual.	Applicant
5. Certificate of Product Registration from the country of origin of the medical device to be used. If the medical device is locally manufactured, copy of the License to Operate as Medical Device Manufacturer.	Principal/Source/Manufacturer
6. Technical description of the medical device from the manufacturer; not downloaded from the company's website.	Principal/Source/Manufacturer
7. Justification letter from the attending physician regarding the urgency of the use of the medical device.	Applicant
8. Medical abstract of the patient.	Applicant
9. A waiver of FDA responsibility from any damage or injury arising from the use of the unregistered medical device to be signed by the applicant company, a relative of the patient and the attending physician.	Applicant

10. A commitment letter from the applicant that a medical report shall be submitted after the operation or use of the medical device in the patient.	Applicant
Submission schedule is as follows: For companies with names beginning with numbers 0-9 and letters A-M: Every Thursday from 8:00 AM to 5:00 PM. For companies with names beginning with letters N-Z: Every Friday from 8:00 AM to 5:00 PM. This schedule applies to working days only and excludes national and declared non-working days. In the event of a holiday/non-working day, then the regular schedule shall be followed on the next working and scheduled submission day	

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME*	PERSON RESPONSIBLE
1. Client sends an email containing the PDF of their application to fdac.letters@fda.gov.ph following the correct schedule.	1 Receiving officer generates a Document Tracking Number (DTN) and sends an acknowledgment email / order of payment to the client	None	Timeline starts after posting of payment	FDA Officer
2. The applicant company receives the Order of Payment and pays the assessed fee through FDAC Cashier or any other means prescribed by FDA. (e.g. BANCNET, LANDBANK ONCOLL) The Order of Payment will only be valid for 24 hours.	2 FDA receives the payment from the applicant company for posting	PHP510.00		FDA Cashier
3. The applicant company receives the official receipt and sends the proof of payment to FDA Action Center (FDAC) through email.	3.1 FDAC forwards the application to CDRRHR.	None		FDAC Officer

	3.2 Data Controller assigns the application to evaluator.	None	1 working day	Data Controller
	3.3 The technical evaluator reviews the application. Recommends approval/disapproval.	None	2 working days	Technical Evaluator
	3.4 Quality Assurance - Checking of recommendation of the Supervisor	None	1 working day	LRD Chief
	3.5 Final Approval/Disapproval and signature of the Director.	None	1 working day	CDRRHR Director
	3.6 Assigning of number and printing of permit. Scanning and transmitting permit to Records Section.	None	1 working day	Administrative Officer
4 Pick-up of Certificate	4 Queuing and endorsement to the FDA Releasing Section.	None	1 working day	AFS Records Officer / Admin Officer
	TOTAL	PHP510.00	7 working days**	

*Day 1 commences upon the receipt of the proof of payment / posting of payment.

**Timeline provided is for applications that are complete and correct with no Notice of Deficiencies issued.

20. ISSUANCE OF FDA CLEARANCE FOR CUSTOMS RELEASE

Clearance for Customs Release (CFCR) is a document issued upon approval of the CDRRHR allowing and informing the release of regulated imports by the Bureau of Customs.

Center/Office/Division	Center for Device Regulation, Radiation Health and Research- Radiation Regulation Division
Classification	Simple
Type of Transaction	G2B- Government to Business
Who May Avail	Importer/Distributor of Radiation Emitting Devices
Fees to be Paid	PHP 310/ Unit

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
1.Written request for issuance of CFCR addressed to the Director of CDRRHR containing the following information documents: Number of units to be imported; Intended use of unit; Name and address of the facility where the unit will be installed (if available)	Applicant
2. A duly notarized letter guaranteeing submission to the CDRRHR of the name and address of the buyer of the device within fifteen (15) days of the sale/transfer of ownership of the device (if name of buyer is unavailable upon application).	Applicant
3.For radiation device item to be used for medical applications, a Certificate of Product Registration (CPR) or any equivalent document certifying that the product is safe and allowed to be sold in the country of origin issued by the Ministry of Health of the country of origin; This document shall be duly authenticated by the Philippine Consulate if the country of origin is a non-apostille member; This document shall be Apostilled if the country of origin is part of the Apostille Convention;	 Philippine Embassy in the country of origin Philippine Embassy in the country of origin Applicant/ Legal Person

If the CPR is unavailable immediately, certificate of free sales and/or a duly notarized letter guaranteeing submission of this document to the CDRRHR, within sixty (60) days from receipt by the CDRRHR of the written request, shall be allowed in lieu of the CPR	

4.	Brochure/ Literature of the device/ devices.	Product Manufacturer
5.	Copy of importer's permit.	Local government where the office of the importer is located
6.	Copy of proforma invoice.	Importer

STEPS FOR THE ISSUANCE OF CLEARANCE FOR CUSTOM RELEASE

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
1. Submits the required documents to FDA through email.	1.1. Decking of application to the assessor for pre-assessment.	-	-	CDRRHR-RRD Data controller
	1.2. Pre-assessment of the applications and attached documents. *If complete, issue order of payment. **If not complete, assessor will send a notification of lacking documents. ***If the noted deficiencies are not submitted on or before the deadline, the application is denied.	-	-	CDRRHR-RRD Assessor
2. The applicant/authorized officer downloads the issued order of payment and pays the corresponding fee to the FDA recognized payment centers.	2.1. The FDA will receive the payment from the applicant for validation and posting.	PHP 310.00/ unit	-	FDA Cashier
	2.2. Evaluation of application. *If correct, application is recommended for the issuance of CFCR.	-	1 working day	CDRRHR-RRD

	**If not, the evaluator shall notify the applicant of the lacking regulatory requirements. ***If the facility fails to comply within the prescribed period, a Letter of Disapproval shall be sent to the facility.			Evaluator
	2.3. Reviews and recommends the draft CFCR/LOD for printing and final approval/disapproval of the Center Director.	-	1 working day	CDRRHR-RRD QA
	2.4. Approves/disapproves and signs CFCR/LOD.	-	1 working day	CDRRHR Director
	2.5 Endorses the CFCR/LOD to the Records Section for release/for mailing.	-		CDRRHR-RRD Data Controller
	TOTAL:	PHP310.00/ unit	3 working days	
Please be advised that as per RA No.11032 IRR, page 22 of 48, Section 3, b) The maximum time prescribed in Section 9 (b) (1) of the Act may be extended only once for the same number of days, which shall be indicated in the Citizen's Charter. Note: *Day 1 commences upon posting of payment.				

21. PRE-OPERATIONAL PERMIT (POP) FOR THERAPEUTIC X-RAY FACILITIES

Pre-operational permit (POP) is an authorization prior to the construction of a therapeutic x-ray facility.

Center/Office/Division	:	Center for Device Regulation, Radiation Health and Research- Radiation Regulation Division
Classification	:	Highly Technical
Type of Transaction	:	G2B- Government to Business
Who May Avail	:	All Therapeutic X-ray Facilities
Fees to be Paid	:	None

CHECKLIST OF REQUIREMENTS	Where to Secure
1. Proof of Business Name and Address of the facility (Mayor's Permit)	Mayor's office from the municipality where the facility is located
2. Design of the medical linear accelerator facility indicating shielding details duly evaluated, verified, and signed by a board-certified ROMP	Equipment Manufacturer
Technical description/specifications of the following equipment: Therapeutic X-ray Machine Treatment planning system Patient data management software if available Radiotherapy simulator or computed tomography simulator, All other equipment listed in Appendix V of AO 2013-0031 or as revised	Equipment Manufacturer
Certification issued by the equipment manufacturer That the Therapeutic X-ray machine in its present condition is compliant with the performance and safety requirements of the International Atomic Energy Agency (IAEA) and the International Organization for Standardization / International Electrotechnical Commission (ISO/IEC) On the availability of spare parts, maintenance, and repair services.	Equipment Manufacturer

Personnel requirements: Notarized contract of employment between the facility and: The radiation oncologist/s The certified radiation oncology medical physicist The radiation oncology medical physicist The four (4) radiologic technologists	Human Resource Department of the Applicant
Radiation Protection and Safety Program	Applicant (in coordination with the Radiation Protection Committee of the hospital)
Emergency procedures during testing, commissioning, internal, and external quality audit, and during clinical operation, including a system of reporting a radiological accident/incident	Applicant (in coordination with their in-house Radiation Oncology Medical Physicist)
Emergency preparedness and response plan in the event of radiological emergencies such as: Accident medical exposure of a patient Accident exposure of a worker Accident exposure of a member of a public	Applicant (in coordination with their in-house Radiation Oncology Medical Physicist)

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
1. Submits the required documents to FDA through email.	1.1. Decking of application to the evaluator for evaluation.	-	-	CDRRHR-RRD Data controller

	1.2. Evaluates the application documents. *If complete and correct, draft POP for quality assurance. **If not, the evaluator shall notify the applicant of the lacking regulatory requirements. ***If the facility fails to comply within the prescribed period, a Letter of Disapproval (LOD) shall be sent to the facility.	-	5 working days	CDRRHR-RRD Evaluator/ Technical Officer
	1.3. Reviews and recommends the POP/LOD for approval to the Center Director.	-	10 working days	CDRRHR-RRD QA
	1.4. Approves/disapproves and signs POP/LOD.	-	3 working days	CDRRHR Director
	1.5 Encodes and endorses the approved POP/LOD to Records Section for releasing/for mailing.	-	2 working days	CDRRHR-RRD Data Controller/AFS Records Personnel
	TOTAL:	None	20 working days	
Please be advised that as per RA No.11032 IRR, page 22 of 48, Section 3, b) The maximum time prescribed in Section 9 (b) (1) of the Act may be extended only once for the same number of days, which shall be indicated in the Citizen's Charter.				

22. ISSUANCE OF SALES PROMO PERMIT (INITIAL APPLICATION)

The application for permit for the conduct of sales promotion schemes for medical devices.

Center/Office/Division	:	CDRRHR-LRD
Classification	:	Complex
Type of Transaction	:	G2B - Government-to-Businesses
Who May Avail	:	Medical Device Manufacturers/Distributors (Importer/Exporter/Wholesaler)/Trader
Fees to be Paid	:	NCR and other regions with prize ranging from Php1.00 to Php 300,000: Php1,000.00 + 1% LRF per certification; NCR and other regions with prize ranging from above Php300,000 to Php500,000: Php2,000.00 + 1% LRF per certification; NCR and other regions with prize ranging from Php500,000 to 1M: Php3,000.00 + 1% LRF per certification; NCR and other regions with prize ranging from above 1M: Php5,000.00 + 1% LRF per certification

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
Letter of Intent for application of Promo Permit Include in the letter if an FDA representative is needed during the raffle date	Applicant/Advertising Agency
Accomplished Information Sheet and Mechanics of the Promotion Detailed list of promo mechanics with date/venue of raffle, prizes, and number of winners if applicable Detailed description on how the winner shall be chosen Promo duration is a must, “while supplies last is unacceptable”	Applicant/Advertising Agency
Copy of the valid product notification/registration/exemption For CMDN’s/CMDR’s currently undergoing the Amendment/Variation process, a letter of approval must be secured by the company prior to promo application.	Distributor/Importer/Manufacturer
Advertising/ Collateral Materials to be used in the Promotion The DOH-FDA promo permit number must be indicated.	Applicant

Valid License to operate as distributor/importer/manufacturer	Distributor/Importer/Manufacturer
Proof of payment	FDA Cashier
Self-Assessment Form	Applicant
Accomplished Integrated Application Form.	Applicant
List of participating products in Excel Format.	Applicant
Submission schedule is as follows: > For companies with names beginning with numbers 0-9 and letters A-M: Every Thursday from 8:00 AM to 5:00 PM. > For companies with names beginning with letters N-Z: Every Friday from 8:00 AM to 5:00 PM. This schedule applies to working days only and excludes national and declared non-working days. In the event of a holiday/non-working day, then the regular schedule shall be followed on the next working and scheduled submission day.	

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
1. Client sends an email containing the PDF of their application to fdac.pacd@fda.gov.ph following the correct schedule. Note: Refer to FDA Circular No. 2020-026	1 Receiving officer generates a Document Tracking Number (DTN) and sends an acknowledgment email / order of payment to the client	None	Timeline starts after posting of payment	FDAC Officer

2. The applicant company receives the Order of Payment and pays the assessed fee through FDAC Cashier or any other means prescribed by FDA. (e.g. BANCNET, LANDBANK ONCOLL)*The Order of Payment will only be valid for 24 hours.	2 The FDA Personnel receives the payment from the applicant company for posting	See above table Php1,010.00/ Php2,020.00/ Php3,030.00/ Php5,050.00		FDA Cashier
3. The applicant company receives the official receipt and sends the proof of payment to FDA Action Center (FDAC) through email	3.1 FDAC forwards the application to CDRRHR.	None		FDAC Officer
	3.2 CDRRHR assigns the application to evaluator	None	1 working day	CDRRHR Administrative Staff
	3.3 The technical evaluator reviews the application. Recommends approval or disapproval.	None	2 working days	Technical Evaluator
	3.4 Quality Assurance - Checking of recommendation of the Supervisor	None	2 working days	LRD Chief
	3.5 Final Approval/Disapproval and signature of the Director.	None	1 working day	CDRRHR Director
	3.6 Assigning number and Printing of permit. Scanning and transmittal of the permit to the Records Section.	None	1 working day	CDRRHR Administrative staff
Pick-up of Certificate	4 Queuing and endorsement to the FDA Releasing Section	None	1 working day	AFS Records Officer / Administrative Officer
	TOTAL	Php1,010.00/ Php2,020.00/ Php3,030.00/ Php5,050.00	7 working days	

*Day 1 commences upon the receipt of the proof of payment / posting of payment.

23. ISSUANCE OF SPECIAL COVID CERTIFICATION (INITIAL APPLICATION AND RE-ISSUANCE)

The application for special certificate issued for COVID-19 test kits.

Center/Office/Division	:	CDRRHR-LRD
Classification	:	Highly Technical
Type of Transaction	:	G2B - Government-to-Businesses
Who May Avail	:	Medical Device Manufacturers/Distributors (Importer/Exporter/Wholesaler)/Trader
Fees to be Paid	:	Php 500.00 + 1% LRF per certificate

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
Letter of intent regarding exemption of the device/product from registration	Applicant
Valid License to Operate as a Medical Device Distributor/Importer/Exporter	Applicant
Product registration issued by the regulatory agency or their accredited third party from the countries with established regulation such as but not limited to US Food and Drug Administration, Therapeutic Goods Authority, European Union, Health Science Authority, Pharmaceutical and Medical Device Authority, Ministry of Food and Drug Safety (Korea), and Health Canada, or WHO pre-qualification or EUL.	Applicant / Principal/Manufacturer
Product profile/IFU indicating the specificity and sensitivity of the COVID-19 test kit.	Applicant / Principal/Manufacturer
NOTES: Submit an electronic/scanned copy (in PDF searchable format of at least 150 dpi) The soft copy should be arranged according to the checklist of requirements. The file name should consist of the name of the requirement. The electronic copy should be contained either in one single continuous file per requirement or single continuous file for all requirements.	

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
1. The applicant company sends and email to fdac.letters@fda.gov.ph. The e-mail should contain the complete application requirements.	1. Receiving officer generates a Document Tracking Number (DTN) and sends an acknowledgment email / order of payment to the client.	None		FDAC Officer
2. The applicant company receives the Order of Payment and pays the assessed fee through FDAC Cashier or any other means prescribed by FDA. (e.g. BANCNET, LANDBANK ONCOLL). The Order of Payment will only be valid for 24 hours. The applicant company receives the official receipt and sends the proof of payment to FDA Action Center (FDAC) through email.	2.1 FDAC receives the payment from the applicant company for posting. FDAC forwards the application to CDRRHR.	P510	Timeline starts after posting of payment	FDAC Officer
	2.2 CDRRHR receives the application and decks the file to the evaluator.	None	1 working day	CDRRHR Administrative Staff
	2.3 Technical evaluation of application. Recommendation for approval/disapproval/endorsement letter to the NRL for performance testing.	None	13 working days	Technical Evaluator

	2.4 Quality Assurance - Checking of recommendation of the Supervisor.	None	3 working days	LRD Chief
	2.5 Final Approval/Disapproval and signature of the Director.	None	2 working days	CDRRHR Director
	2.6 Scanning and transmittal of certificate or letter to the FDA Records Section.	None	1 working day	CDRRHR Administrative Staff
	2.7 Queuing and endorsement to the FDA Releasing Section.	None	1 working day	AFS Records Officer / Administrative Officer
	TOTAL		20 working days**	

24.MANUAL APPLICATION OF RADIATION FACILITIES

24.1. ISSUANCE OF CERTIFICATE OF COMPLIANCE (COC)

Certificate of Compliance (COC) is a form of authorization/permission granted by the FDA which serves as proof of the facility's compliance to the set technical requirements. It is a prerequisite for the issuance of the DOH-LTO.

Center/Office/Division	Center for Device Regulation, Radiation Health and Research- Radiation Regulation Division
Classification	Highly Technical
Type of Transaction	G2B- Government to Business
Who May Avail	All Medical and Non-Medical X-ray Facilities under One-Stop-Shop Licensing System
Fees to be Paid	Refer to table below

mA RANGE	INITIAL (3 years)	RENEWAL (5 years)	Renewal of Expired Authorization				
			1st Month	2nd Month	3rd Month	4th Month	> 4 months
100 and below	2430.00	2050.00	6250.00	6450.00	6650.00	6850.00	7230.00
101 up to 300	3333.00	2800.00	8575.00	8575.00	9125.00	9400.00	9933.00
301 up to 500	4242.00	3550.00	10900.00	11250.00	11600.00	11950.00	12642.00
501 up to 700	5151.00	4300.00	13225.00	13650.00	14075.00	14500.00	15351.00
greater than 700	6060.00	5050.00	15550.00	16050.00	16550.00	17050.00	18060.00

CERTIFICATE OF COMPLIANCE DOCUMENTARY REQUIREMENTS

MEDICAL X-RAY FACILITY

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
1. Duly accomplished medical x-ray license application form **(Initial/ Renewal)**	Applicant
2. Proof of subscription to personal dose monitor (TLD or OSL) from authorized personal dosimetry service provider **(Initial & Renewal)**	DTI-PAB Accredited Personal Dosimetry Service Providers
3. VALID Professional Regulation Commission (PRC) license of all the radiologist/s and radiologic/x-ray technologist/s. **(Initial & Renewal)**	Professional Regulation Commission
4. Certificate of all the radiologist/s for being a Fellow of the Philippine College of Radiology (FPCR) or Diplomate of the Philippine Board of Radiology (DPBR) **(Initial & Renewal)**	Philippine College of Radiology
5. For Radiologic/ X-ray Technologist who will act as the radiation protection officer, certificate of training on radiation protection as proof that he completed the RPO training. **(Initial & Renewal with changes in RPO)**	Recognized training provider of FDA
6. For Medical Physicist who will act as the radiation protection officer (RPO), photocopy of the documentary evidence satisfying the provisions stated in section 2.29 of AO No. 35 s. 1994. **(Initial & Renewal with changes in RPO)**	Applicant
7. Photocopy of performance test report from FDA – CSL/DTI – PAB accredited testing body (CT-Scan and Mammography) **(Initial &** Amendment)	FDA – CSL/DTI – PAB accredited testing body service providers
8. Mayor's Permit as proof of facility business name and address **(Initial)**	Mayor's office from the municipality where the facility is located
9. Machine Calibration Report duly signed by the Service Engineer **(Initial &** Major Variation)	Service Engineer of the facility/ supplier/ third party service providers
10. Photocopy of the latest DOH License to Operate (LTO) /Certificate of Accreditation (COA). **(Renewal Only)**	Applicant
11. Duly filled-up and notarized affidavit of continuous compliance. **(Renewal Only)**	Applicant

DENTAL X-RAY FACILITY

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
1. Duly accomplished application form **(Initial & Renewal)**	Applicant
2. Proof of subscription to personal dose monitor (TLD or OSL) from authorized personal dosimetry service provider **(Initial & Renewal)**	DTI-PAB Accredited Personal Dosimetry Service Providers
3. Certificate of training of the dentist and/or radiologic/x-ray technologist in radiation protection for radiation safety officers of dental x-ray facilities conducted by an organization recognized by CDRRHR (Initial & Renewal Application with new/changed RPO)	Recognized training provider of FDA
4. VALID Professional Regulation Commission (PRC) license of all the radiologist/s and radiologic/x-ray technologist/s. **(Initial & Renewal)**	Professional Regulation Commission
5. Mayor's Permit as proof of facility business name and address **(Initial)**	Mayor's office from the municipality where the facility is located
6. Machine Calibration Report duly signed by the Service Engineer **(Initial & Major Variation)** (except Periapical Machine)	Service Engineer of the facility/ supplier/ third party service providers
7. Photocopy of performance test report from FDA – CSL/DTI – PAB accredited testing body **(Initial Applications for CBCT)**	FDA – CSL/DTI – PAB accredited testing body service providers
8. Photocopy of the latest DOH License to Operate (LTO) /Certificate of Accreditation (COA). **(Renewal Only)**	Applicant
9. Duly filled-up and notarized affidavit of continuous compliance. **(Renewal Only)**	Applicant

24.2.ISSUANCE OF CERTIFICATE OF REGISTRATION (COR) FOR MAGNETIC RESONANCE IMAGING

Refers to Non-ionizing Radiation Facility and device that uses radiofrequency radiation devices that produces (either deliberately or incidentally) radiofrequency energy during the course of their operation. It uses strong magnetic fields, magnetic field gradients and radio waves to generate images of the organs of the body for diagnosis human diseases.

Center/Office/Division	Center for Device Regulation, Radiation Health and Research- Radiation Regulation Division
Classification	Highly Technical
Type of Transaction	G2B- Government to Business
Who May Avail	All Magnetic Resonance Imaging (MRI) Facilities
Fees to be Paid	Refer to table below

INITIAL (3 years)	RENEWAL (5 years)	Renewal of Expired COR				
		1st Month	2nd Month	3rd Month	4th Month	> 4 months
6060.00	5050.00	15550.00	16050.00	16550.00	17050.00	18060.00

CERTIFICATE OF REGISTRATION (COR) DOCUMENTARY REQUIREMENTS

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
1. Duly accomplished MRI registration form **(Initial/ Renewal)**	Applicant
2. VALID Professional Regulation Commission (PRC) license of all the radiologist/s and radiologic technologist/s. **(Initial & Renewal)**	Professional Regulation Commission
3. Photocopy of the certificate of all the radiologist/s for being a Fellow of the Philippine College of Radiology (FPCR) or Diplomate of the Philippine Board of Radiology (DPBR)**. (Initial & Renewal)**	Philippine College of Radiology
4. Mayor's Permit as proof of facility business name and address **(Initial)**	Mayor's office from the municipality where the facility is located
6. Radiofrequency/Magnetic Field map. **(Initial Only)**	Applicant
7. Photocopy of the latest Certificate of Registration. **(Renewal Only)**	Applicant

24.3.ISSUANCE OF LTO FOR THERAPEUTIC X-RAY FACILITY (Utilizing LINAC)

License to Operate issued to an x-ray facility utilizing Linear Accelerator, Tomotherapy, Intraoperative Radiation Therapy or any other radiation devices that are used for treatment of cancer diseases.

Center/Office/Division	Center for Device Regulation, Radiation Health and Research- Radiation Regulation Division
Classification	Highly Technical
Type of Transaction	G2B- Government to Business
Who May Avail	All Therapeutic X-ray Facilities
Fees to be Paid	Refer to table below

INITIAL (3 years)	RENEWAL (5 years)	Renewal of Expired LTO				
		1st Month	2nd Month	3rd Month	4th Month	> 4 months
6060.00	5050.00	15550.00	16050.00	16550.00	17050.00	18060.00

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
1. Pre-operational Permit (POP) **(Initial only)**	Applicant
2. Proof of subscription to personal dose monitor (TLD or OSL) from authorized personal dosimetry service provider **(Initial & Renewal)**	DTI-PAB Accredited Personal Dosimetry Service Providers
3. PROS or PBR-RO certificate/s and valid professional regulation commission (PRC) license/s of all the radiation oncologist/s working in the therapeutic x-ray facility **(Initial & Renewal)**	Philippine Radiation Oncology Society/ Philippine Board of Radiology in Radiation Oncology
4. PRC board certificates and valid PRC licenses of all the radiotherapy technologists and their certificates of training as prescribed in Section VI-A-4.3 of the A.O. No. 0031 series of 2013 or as revised **(Initial & Renewal)**	Professional Regulation Commission

5. Philippine Board of Medical Physics certificate/s of all the Radiation Oncology Medical Physicist (ROMP). For non-board ROMPs, documentary evidence satisfying the provisions stated in Section XV-C-2 of the A.O. No. 0031 series of 2013 **(Initial & Renewal)**	Training Certificates- Senior Radiotherapy Technologist/ Certified Medical Physicist- Radiation Oncology Medical Physicist of the facility, Supplier's application specialist, Professional Organization of Radiologic Technologists
6. Valid notarized contract of employment between the facility and the radiation oncologist/s, radiation oncology medical physicist/s, and radiotherapy technologists **(Initial & Renewal)**	Applicant
7. Notarized appointment of the Radiation Protection Officer (RPO) and Assistant RPO **(Initial & Renewal)**	Applicant
8. Where applicable, proof of qualification/recognition as a Qualified Expert (Initial & Renewal)	Philippine Board of Medical Physics
9. Acceptance Test Certificate signed by the technical representative of the equipment manufacturer/supplier and board-certified ROMP (if available upon filing of application) **(Initial Only)**	Applicant in coordination with their Equipment manufacturer/supplier
10. Commissioning report of the equipment duly signed by the facility's certified ROMP **(Initial Only)**	Applicant (in coordination with their in-house Certified Medical Physicist- Radiation Oncology Medical Physicist)
11. Performance testing report of the x-ray unit/s in the therapeutic x-ray facility. (Initial Only)	FDA – CSL/DTI – PAB accredited testing body service providers
12. LINAC output calibration report of the DOH-SSDL or of a third-party board-Certified ROMP **(Initial & Renewal)**	DOH- SSDL or of a third-party board-Certified ROMP
13. Copy of the latest License to Operate **(Renewal Only)**	Applicant

24.4. AMENDMENT OF COC, LTO (MANUAL) AND COR DOCUMENTARY REQUIREMENTS

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
CHANGE OF AUTHORIZED PERSONNEL Letter request stating the changes of authorized personnel Duly accomplished x-ray application form Proof of subscription to personal dose monitor (TLD or OSL) from authorized personal dosimetry service provider if applicable. Proof of qualification of the new personnel as required in the application from checklist of requirements Copy of existing DOH LTO/COA	Applicant DTI-PAB Accredited Personal Dosimetry Service Providers Applicant Applicant Applicant
CHANGE OF MANAGEMENT OR OWNERSHIP Letter request stating the changes of the management/ownership/legal person Duly accomplished x-ray application form DTI/SEC registration/MOA/ Resolution/Mayor's Permit under the name of the new owner/management Copy of existing DOH LTO/COA	Applicant Applicant Mayor's office from the municipality where the facility is located/ DTI/ Securities and Exchange Commission Applicant
REMOVAL OF MACHINE Duly accomplished x-ray application form Letter of request stating the reason/s for the removal of machine Copy of existing DOH LTO/COA	Applicant
CHANGE IN THE RADIATION FACILITY SERVICE CATEGORY Duly accomplished x-ray application form Letter request stating the change in the radiation facility service category For upgrading of facility service category, floor plan is required as proof that the x-ray room specifications are met Copy of existing DOH LTO/COA	Applicant

INCLUSION OF ADDITIONAL MACHINE/S Duly accomplished x-ray application form Letter request stating the changes of machine details and/or inclusion of additional machine Machine Calibration Report duly signed by the Service Engineer Photocopy of performance test report from FDA – CSL/DTI – PAB accredited testing body (CT-Scan and Mammography) Copy of existing DOH LTO/COA *Initial fee for the particular machine shall apply and may be subject to inspection as deemed necessary.	Applicant Service Engineer of the facility/ supplier/ third service party FDA – CSL/DTI – PAB accredited testing body service providers
CHANGE OF MACHINE OR REPLACEMENT OF MAJOR COMPONENTS OF X-RAY MACHINE Duly accomplished x-ray application form Letter request stating the changes in the machine and/or its parts Machine Calibration Report duly signed by the Service Engineer Photocopy of performance test report from FDA – CSL/DTI – PAB accredited testing body (CT-Scan and Mammography) Copy of existing DOH LTO/COA *Initial fee for the particular machine shall apply and may be subject to inspection as deemed necessary.	 Applicant Applicant Service Engineer of the facility/ supplier/ third service party FDA – CSL/DTI – PAB accredited testing body service providers Applicant

25.ONLINE APPLICATION OF RADIATION FACILITIES

25.1. ISSUANCE OF USER'S ACCOUNT

Radiation Regulation Division Portal (RRD Portal) User Account will be used as the log in credentials in applying authorizations covered in the RRD Portal. The user account applicant shall either be the owner or authorized person of the facility/company.

Center/Office/Division	Center for Device Regulation, Radiation Health and Research- Radiation Regulation Division
Classification	Simple
Type of Transaction	G2B- Government-to-Business
Who May Avail	All Radiation Facilities applying through RRD Portal
Fees to be Paid	None

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
1. Letter of Intent or Authorization Letter	Authorized person/ Legal person/ Owner of the Facilities/Company
2. Sworn Undertaking Form (CSE only)	Authorized personnel of Telecommunication Companies, RADAR, AM/FM Broadcast Station, TV Station, Radiofrequen Radiation (RFR) facilities, Contractors and Subcontractors of telecommunications companies/ service providers

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
1. Go to https://rrdportal.fda.gov.ph, click "Create User Account" then select the type of authorization and upload documentary requirements.	1. Validation of user's information and approval of registration. *If approved, client will receive a system generated user name and password in their email account.		2 working days	User Account Evaluator
	TOTAL:	None	Working days	

25.2.ISSUANCE OF CERTIFICATE OF SAFETY EVALUATION (CSE)

Certificate of Safety Evaluation (CSE) is an evaluation of the NIR Facility using specific NIR devices, based on the technical documents submitted regarding the NIR emitting device, nature of installation, location and site configuration of the facility.

Center/Office/Division	Center for Device Regulation, Radiation Health and Research- Radiation Regulation Division
Classification	Highly Technical
Type of Transaction	G2B- Government-to-Business
Who May Avail	All Telecommunication Companies, RADAR, AM/FM Broadcast Station, TV Station, Radiofrequency Radiation (RFR) facilities, Contractors and Subcontractors of telecommunications companies/ service providers
Fees to be Paid	PHP 900/ Transmitter

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
1. Conceptual/ Elevation drawing (Outdoor Antennas)	Licensed Engineer of Telecommunications Companies /Service providers /Contractors/Subcontractors
2. Floor Plan (Indoor Antennas)	Licensed Engineer of Telecommunications Companies /Service providers /Contractors/Subcontractors
3. NTC Permit (RADAR, AM/FM Broadcast Station, TV Station)	National Telecommunications Commission (NTC)
4. Brochure/ Literature of the Antenna (RADAR)	Supplier/ Manufacturer of Antenna

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
1. Encode required fields in the on-line application and upload the documentary requirements.	1. Pre-assessment of the on-line applications and attached documents. *If complete, order of payment will be generated. **If not, a system generated notification will be sent to the facility stating that the application is hereby denied.		-	CDRRHR-RRD Assessor
2. Download, print order of payment, pay the corresponding fee at the FDA	2. Validation and posting of payment.	Php 900.00/ Transmitter	-	FDA Cashier
	2.2. Reviews and recommends the draft CSE/LOD to the Center Director for final approval/ disapproval.		12 working days	CDRRHR-RRD QA
	2.3. Approves/ disapproves CSE/LOD. *If approved, client will receive a system generated CSE in their email account. **If not, client will receive a disapproval letter in their email account.		8 working days	CDRRHR Director
3. Download and print the issued CSE/LOD.			-	Applicant
	TOTAL:	Php 900.00/ Transmitter	20 working days	

23.3.ISSUANCE OF LICENSE TO OPERATE (LTO) OF X-RAY FACILITIES

License to Operate (LTO) refers to an authorization or permission granted by the FDA to any natural or juridical person engaged in the use of radiation devices and operation of its facilities and activities, where the level of risk, potential magnitude of exposure and hazards of facilities and activities associated with the practice or use of radiation devices is high.

Center/Office/Division	:	Center for Device Regulation, Radiation Health and Research- Radiation Regulation Division
Classification	:	Highly Technical
Type of Transaction	:	G2B- Government-to-Business
Who May Avail	:	Medical X-ray Facilities such as General Radiography/Fluoroscopy, Mammography, Interventional Radiography, Computed Tomography and Therapeutic X-ray facility Utilizing Linear Accelerator. Non-Medical X-ray Facilities such as Anti-Crime & Linear Accelerator for Anti-Crime Applications Industrial X-ray Facilities such as Open-type Industrial Radiography, Linear Accelerator for Industrial Application, Computed Tomography for Industrial Application, Non-destructive Testing. Dental X-ray Facilities such as Panoramic/Cephalometric, CBCT, Veterinary X-ray Facilities
Fees to be Paid	:	Refer to table below

mA RANGE	INITIAL (3 years)	RENEWAL (5 years)	Renewal of Expired Authorization				
			1st Month	2nd Month	3rd Month	4th Month	> 4 months
100 and below	2430.00	2050.00	6250.00	6450.00	6650.00	6850.00	7230.00
101 up to 300	3333.00	2800.00	8575.00	8575.00	9125.00	9400.00	9933.00
301 up to 500	4242.00	3550.00	10900.00	11250.00	11600.00	11950.00	12642.00
501 up to 700	5151.00	4300.00	13225.00	13650.00	14075.00	14500.00	15351.00
greater than 700	6060.00	5050.00	15550.00	16050.00	16550.00	17050.00	18060.00

LTO DOCUMENTARY REQUIREMENTS
MEDICAL X-RAY FACILITY

GENERAL RADIOGRAPHY / FLUOROSCOPY AND INTERVENTIONAL

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
Mayor's Permit as proof of facility business name and address **(Initial)**	Mayor's office from the municipality where the facility is located
Proof of subscription to personal dose monitor (TLD or OSL) from authorized personal dosimetry service provider **(Initial & Renewal)**	DTI-PAB Accredited Personal Dosimetry Service Providers
Valid professional regulation commission (PRC) license of all radiologist/s and radiologic/x-ray technologist/s **(Initial & Renewal)**	Professional Regulation Commission
Certificate for being a fellow of the Philippine College of Radiology (FPCR) or diplomate of the Philippine Board of Radiology (DPBR) of all Radiologist/s **(Initial & Renewal)**	Philippine College of Radiology
For Radiologic/ X-ray Technologist who will act as the radiation protection officer, certificate of training on radiation protection as proof that he completed the RPO training. **(Initial & Renewal with changes in RPO)**	Recognized training provider of FDA
For Medical Physicist who will act as the radiation protection officer (RPO), photocopy of the documentary evidence satisfying the provisions stated in section 2.29 of AO No. 35 s. 1994. **(Initial & Renewal with changes in RPO)**	Applicant
If transportable, valid vehicle LTO registration (OR/CR) **(Initial & Renewal)**	Land Transportation Office
Machine Calibration Report duly signed by the Service Engineer **(Initial & Renewal)**	Service Engineer of the facility/ supplier/ third party service providers
Copy of the latest License to Operate **(Renewal Only)**	Applicant

COMPUTED TOMOGRAPHY / MAMMOGRAPHY

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
Mayor's Permit as proof of facility business name and address **(Initial)**	Mayor's office from the municipality where the facility is located
Proof of subscription to personal dose monitor (TLD or OSL) from authorized personal dosimetry service provider **(Initial & Renewal)**	DTI-PAB Accredited Personal Dosimetry Service Providers
Valid professional regulation commission (PRC) license of all radiologist/s and radiologic/x-ray technologist/s **(Initial & Renewal)**	Professional Regulation Commission
Certificate for being a fellow of the Philippine College of Radiology (FPCR) or diplomate of the Philippine Board of Radiology (DPBR) of all Radiologist/s **(Initial & Renewal)**	Philippine College of Radiology
For Radiologic/ X-ray Technologist who will act as the radiation protection officer, certificate of training on radiation protection as proof that he completed the RPO training. **(Initial & Renewal with changes in RPO)**	Recognized training provider of FDA
For Medical Physicist who will act as the radiation protection officer (RPO), photocopy of the documentary evidence satisfying the provisions stated in section 2.29 of AO No. 35 s. 1994. **(Initial & Renewal with changes in RPO)**	Applicant
If transportable, valid vehicle LTO registration (OR/CR) **(Initial & Renewal)**	Land Transportation Office
Performance test report from FDA-CSL/DTI-PAB accredited testing body **(Initial & Major Variation)**	FDA – CSL/DTI – PAB accredited testing body/ service provider

Copy of the latest License to Operate **(Renewal Only)**	Applicant

MEDICAL X-RAY FACILITIES
ANTI-CRIME (Utilizing LINAC)

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
Mayor's Permit as proof of facility business name and address **(Initial)**	Mayor's office from the municipality where the facility is located
Proof of subscription to personal dose monitor (TLD or OSL) from authorized personal dosimetry service provider **(Initial & Renewal)**	DTI-PAB Accredited Personal Dosimetry Service Providers
Certificate of training of the radiation protection officer (RPO) in an appropriate radiation protection training course conducted by an organization recognized by the CDRRHR **(Initial & Renewal)**	Recognized training provider of FDA
Provision of radiation survey meter **(Initial & Renewal)**	Supplier of Radiation Survey Meter/ Calibration Services Providers
Valid Radiation Survey Meter Calibration Certificate **(Initial & Renewal)**	
If transportable, valid vehicle LTO registration (OR/CR) **(Initial & Renewal)**	Land Transportation Office
Brochure/Literature of the machine **(Initial & Renewal)**	Machine Manufacturer/Supplier
Copy of the latest License to Operate **(Renewal Only)**	Applicant

EDUCATION, TRAINING AND RESEARCH

CHECKLIST OF	WHERE TO SECURE
Mayor's Permit as proof of facility business	Mayor's office from the municipality where the facility is located
Proof of subscription to personal dose	DTI- PAB
Valid professional regulation	Professional Regulation Commission
Certificate of training on	Recognized training provider of FDA
If transportable, valid vehicle	Land Transportation Office
Machine Calibration	Service Engineer of the facility/ supplier/ third party service providers

INDUSTRIAL (OPEN-TYPE INDUSTRIAL RADIOGRAPHY, NON-DESTRUCTIVE TESTING and APPLICATIONS UTILIZING LINAC and COMPUTED TOMOGRAPHY)

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
Mayor's Permit as proof of facility business name and address **(Initial)**	Mayor's office from the municipality where the facility is located
Proof of subscription to personal dose monitor (TLD or OSL) from authorized personal dosimetry service provider **(Initial & Renewal)**	DTI-PAB Accredited Personal Dosimetry Service Providers
Certificate of training of the radiation protection officer (RPO) in an appropriate radiation protection training course conducted by an organization recognized by the CDRRHR **(Initial & Renewal with changes in RPO)**	Recognized training provider of FDA
Provision of radiation survey meter **(Initial & Renewal)**	Supplier of Radiation Survey Meter Calibration Services providers
Valid Radiation Survey Meter Calibration Certificate **(Initial & Renewal)**	
If transportable, valid vehicle LTO registration (OR/CR) **(Initial & Renewal)**	Land Transportation Office
Brochure/Literature of the machine **(Initial & Renewal)**	Machine Manufacturer/Supplier
Periodic workplace area monitoring results within the validity period of the expired license **(For facilities with OSL exemption) (Renewal Only)**	Radiation Protection Officer of the facility
Copy of the latest License to Operate **(Renewal Only)**	Applicant

DENTAL (PANORAMIC/CEPHALOMETRIC AND CBCT)

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
Mayor's Permit as proof of facility business name and address **(Initial)**	Mayor's office from the municipality where the facility is located
Proof of subscription to personal dose monitor (TLD or OSL) from authorized personal dosimetry service provider **(Initial & Renewal)**	DTI-PAB Accredited Personal Dosimetry Service Providers
Valid professional regulation commission (PRC) license of all dentist/s and radiologic/x-ray technologist/s **(Initial & Renewal)**	Professional Regulation Commission
Certificate of training of the radiation protection officer (RPO) on radiation protection for radiation safety officers of dental x-ray facilities conducted by an organization recognized by CDRRHR **(Initial & Renewal with changes in RPO)**	Recognized training provider of FDA
If transportable, valid vehicle LTO registration (OR/CR) **(Initial & Renewal)**	Land Transportation Office
Machine Calibration Report duly signed by the Service Engineer **(Initial & Major Variation)**	Service Engineer of the facility/ supplier/ third party service providers
Copy of the latest License to Operate **(Renewal Only)**	Applicant

VETERINARY

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
Mayor's Permit as proof of facility business name and address **(Initial)**	Mayor's office from the municipality where the facility is located
Proof of subscription to personal dose monitor (TLD or OSL) from authorized personal dosimetry service provider **(Initial & Renewal)**	DTI-PAB Accredited Personal Dosimetry Service Providers
Valid professional regulation commission (PRC) license of all veterinarian/s and radiologic/x-ray technologist/s **(Initial & Renewal)**	Professional Regulation Commission
Certificate of training of the radiation protection officer (RPO) on radiation protection for radiation safety officers of veterinary x-ray facilities conducted by an organization recognized by CDRRHR **(Initial & Renewal with changes in RPO)**	Recognized training provider of FDA
Machine Calibration Report duly signed by the Service Engineer **(Initial & Major Variation)**	Service Engineer of the facility/ supplier/ third party service providers
If transportable, valid vehicle LTO registration (OR/CR) **(Initial & Renewal)**	Land Transportation Office
Brochure/Literature of the machine **(Initial & Renewal)**	Machine Manufacturer/Supplier
Copy of the latest License to Operate **(Renewal Only)**	Applicant

23.4.ISSUANCE OF CERTIFICATE OF FACILITY REGISTRATION (CFR) OF X-RAY FACILITIES

Certificate of Facility Registration (CFR) refers to an authorization or permission granted by the FDA to any natural or juridical person engaged in the use of radiation devices and operation of its facilities and activities of medium risk.

Center/Office/Division	:	Center for Device Regulation, Radiation Health and Research- Radiation Regulation Division
Classification	:	Highly Technical
Type of Transaction	:	G2B- Government-to-Business
Who May Avail	:	Medical X-ray Facilities such as Bone Densitometry (DEXA) Non-Medical X-ray Facilities such as Anti-Crime- Security and Baggage Inspection System Industrial X-ray Facilities such as Closed-type industrial radiography Dental X-ray Facilities such as Periapical.
Fees to be Paid	:	Refer to table below

mA RANGE	INITIAL (3 years)	RENEWAL (5 years)	Renewal of Expired Authorization				
			1st Month	2nd Month	3rd Month	4th Month	> 4 months
100 and below	2430.00	2050.00	6250.00	6450.00	6650.00	6850.00	7230.00
101 up to 300	3333.00	2800.00	8575.00	8575.00	9125.00	9400.00	9933.00
301 up to 500	4242.00	3550.00	10900.00	11250.00	11600.00	11950.00	12642.00
501 up to 700	5151.00	4300.00	13225.00	13650.00	14075.00	14500.00	15351.00
greater than 700	6060.00	5050.00	15550.00	16050.00	16550.00	17050.00	18060.00

MEDICAL X-RAY FACILITY (BONE DENSITOMETRY)

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
Mayor's Permit as proof of facility business name and address **(Initial)**	Mayor's office from the municipality where the facility is located
Proof of subscription to personal dose monitor (TLD or OSL) from authorized personal dosimetry service provider **(Initial & Renewal)**	DTI-PAB Accredited Personal Dosimetry Service Providers
Valid professional regulation commission (PRC) license of all radiologist/s and radiologic/x-ray technologist/s **(Initial & Renewal)**	Professional Regulation Commission
Certificate for being a fellow of the Philippine College of Radiology (FPCR) or diplomate of the Philippine Board of Radiology (DPBR) of all Radiologist/s **(Initial & Renewal)**	Philippine College of Radiology
For Radiologic/ X-ray Technologist who will act as the radiation protection officer, certificate of training on radiation protection as proof that he completed the RPO training. **(Initial & Renewal with changes in RPO)**	Recognized training provider of FDA
For Medical Physicist who will act as the radiation protection officer (RPO), photocopy of the documentary evidence satisfying the provisions stated in section 2.29 of AO No. 35 s. 1994. **(Initial & Renewal with changes in RPO)**	Applicant
If transportable, valid vehicle LTO registration (OR/CR) **(Initial & Renewal)**	Land Transportation Office
Copy of the latest Authorization **(Renewal Only)**	Applicant

NON-MEDICAL X-RAY FACILITY

ANTI-CRIME (SECURITY AND BAGGAGE INSPECTION SYSTEM)

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
Mayor's Permit as proof of facility business name and address **(Initial)**	Mayor's office from the municipality where the facility is located
Proof of subscription to personal dose monitor (TLD or OSL) from authorized personal dosimetry service provider **(Initial & Renewal)**	DTI-PAB Accredited Personal Dosimetry Service Providers
Certificate of training of the radiation protection officer (RPO) in an appropriate radiation protection training course conducted by an organization recognized by the CDRRHR **(Initial & Renewal with changes in RPO)**	Recognized training provider of FDA
Provision of radiation survey meter **(Initial & Renewal)**	Supplier of Radiation Survey Meter/ Calibration Services providers
Valid Radiation Survey Meter Calibration Certificate **(Initial & Renewal)**	
If transportable, valid vehicle LTO registration (OR/CR) **(Initial & Renewal)**	Land Transportation Office
Brochure/Literature of the machine **(Initial & Renewal)**	Machine Manufacturer/Supplier
Periodic workplace area monitoring results within the validity period of the expired license **(For facilities with OSL exemption) (Renewal Only)**	Radiation Protection Officer of the facility
Copy of the latest Authorization **(Renewal Only)**	Applicant

INDUSTRIAL (CLOSED-TYPE INDUSTRIAL RADIOGRAPHY)

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
Proof of Business Name (SEC or DTI Registration or Mayor' Business Permit) **(Initial)**	Mayor's office from the municipality where the facility is located/ Department of Trade and Industry/ Securities and Exchange Commission
Proof of subscription to personal dose monitor (TLD or OSL) from authorized personal dosimetry service provider **(Initial & Renewal)**	DTI-PAB Accredited Personal Dosimetry Service Providers
Certificate of training of the radiation protection officer (RPO) in an appropriate radiation protection training course conducted by an organization recognized by the CDRRHR **(Initial & Renewal with changes in RPO)**	Recognized training provider of FDA
Provision of radiation survey meter **(Initial & Renewal)**	Supplier of Radiation Survey Meter Calibration Services providers
Valid Radiation Survey Meter Calibration Certificate **(Initial & Renewal)**	
Periodic workplace area monitoring results within the validity period of the expired license **(For facilities with OSL exemption) (Renewal Only)**	Radiation Protection Officer of the facility
Brochure/Literature of the machine **(Initial & Renewal)**	Machine Manufacturer/Supplier
If transportable, copy of valid vehicle LTO registration (OR/CR) **(Initial & Renewal)**	Land Transportation Office
Copy of the latest Authorization **(Renewal Only)**	Applicant

DENTAL (PERIAPICAL)

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
Proof of Business Name (SEC or DTI Registration or Mayor' Business Permit) **(Initial)**	Mayor's office from the municipality where the facility is located/ Department of Trade and Industry/ Securities and Exchange Commission
Proof of subscription to personal dose monitor (TLD or OSL) from authorized personal dosimetry service provider **(Initial & Renewal)**	DTI-PAB Accredited Personal Dosimetry Service Providers
Valid professional regulation commission (PRC) license of all dentist/s and radiologic/x-ray technologist/s **(Initial & Renewal)**	Professional Regulation Commission
Certificate of training of the radiation protection officer (RPO) on radiation protection for radiation safety officers of dental x-ray facilities conducted by an organization recognized by CDRRHR **(Initial & Renewal with changes in RPO)**	Recognized training provider of FDA
If transportable, valid vehicle LTO registration (OR/CR) **(Initial & Renewal)**	Land Transportation Office
Copy of the latest Authorization **(Renewal Only)**	Applicant

23.5.ISSUANCE OF MAJOR AND MINOR VARIATION OF LICENSE TO OPERATE (LTO) and CERTIFICATE OF FACILITY REGISTRATION (CFR)

Variation is a post-FDA approval changes in the status, condition or activity of an authorized radiation facility.

Center/Office/Division	:	Center for Device Regulation, Radiation Health and Research- Radiation Regulation Division
Classification	:	Highly Technical
Type of Transaction	:	G2B- Government-to-Business
Who May Avail	:	Medical X-ray Facilities such as Bone Densitometry (DEXA) Non-Medical X-ray Facilities such as Anti-Crime- Security and Baggage Inspection System Industrial X-ray Facilities such as Closed-type industrial radiography Dental X-ray Facilities such as Periapical, General Radiography/Fluoroscopy, Mammography, Interventional Radiography, Computed Tomography and Therapeutic X-ray facility Utilizing Linear Accelerator. Non-Medical X-ray Facilities such as Anti-Crime & Linear Accelerator for Anti-Crime Applications Industrial X-ray Facilities such as Open-type Industrial Radiography, Linear Accelerator for Industrial Application, Computed Tomography for Industrial Application, Non-destructive Testing.
Fees to be Paid	:	Refer to table below

mA RANGE	INITIAL (3 years)	RENEWAL (5 years)	Renewal of Expired Authorization				
			1st Month	2nd Month	3rd Month	4th Month	> 4 months
100 and below	2430.00	2050.00	6250.00	6450.00	6650.00	6850.00	7230.00
101 up to 300	3333.00	2800.00	8575.00	8575.00	9125.00	9400.00	9933.00
301 up to 500	4242.00	3550.00	10900.00	11250.00	11600.00	11950.00	12642.00
501 up to 700	5151.00	4300.00	13225.00	13650.00	14075.00	14500.00	15351.00
greater than 700	6060.00	5050.00	15550.00	16050.00	16550.00	17050.00	18060.00

MAJOR VARIATION	
CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
Physical transfer of the radiation facility Letter request stating the changes of location of the facility Mayor's Permit of the Facility	 Applicant Mayor's office from the municipality where the facility is located
Change of location of the machine within the facility Letter request stating the changes of location of the machine from one room to another. Machine Calibration Report duly signed by the Service Engineer	Applicant Service Engineer of the facility/ supplier/ third party service providers
Change of machine or inclusion of additional machine/s Letter request stating the changes of the machine and/or inclusion of additional machine. Machine Calibration Report duly signed by the Service Engineer	Applicant Service Engineer of the facility/ supplier/ third party service providers
Note: *For authorization with more than three years validity, initial fee for the first three years plus renewal fee for the remaining years shall apply for a particular machine and may be subject to inspection as deemed necessary. **For authorization with less than three years validity, initial fee per year shall apply for a particular machine and may be subject to inspection	

MINOR VARIATION	
CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
Change of Business Name of the Radiation Facility Letter request stating the changes of the facility name Updated DTI/SEC registration/Mayor's Permit	 Applicant Mayor's office from the municipality where the facility is located/ Department of Trade and Industry/ Securities and Exchange Commission

Change of Management/Ownership/Legal Person Letter request stating the changes of the management/ownership/legal person DTI/SEC registration/MOA/ Resolution/Mayor's Permit under the name of the new owner/management	Applicant Mayor's office from the municipality where the facility is located/ Department of Trade and Industry/ Securities and
Change of Authorized Personnel Letter request stating the changes of authorized personnel Proof of subscription to personal dose monitor (TLD or OSL) from authorized personal dosimetry service provider where applicable; Proof of qualification of the new personnel as required in the application form checklist of requirements; and	Applicant DTI-PAB Accredited Personal Dosimetry Service Providers Applicant
Removal of Machine Letter request stating the reason/s for the removal of the machine	Applicant
Change in the radiation facility service category Letter request stating the change in the radiation facility service category For upgrading of facility service category, floor plan is required as proof that the x-ray room specifications are met	Applicant Applicant
Correction of Details in the LTO Letter request stating the reason for correction Proof of correct details (i.e. photos of the stickers of the control console and x-ray tube indicating the serial numbers, installation report, preventive maintenance report, supporting documents etc.)	Applicant

STEPS FOR INITIAL APPLICATION FOR A LICENSE TO OPERATE (LTO) AND MAJOR VARIATION

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
1. Encode required fields in the on-line application and upload the documentary requirements.	1. Pre-assessment of the on-line applications and attached documents. *If complete, order of payment will be generated. **If not, a system generated notification will be sent to the facility stating that the	-	-	CDRRHR-RRD Assessor
2. Download, print order of payment, pay the corresponding fee at the FDA recognized	2.1. Validation and posting of payment.	Refer to Table of Fees Above	-	FDA Cashier
	2.2. Queuing/ decking of application to the	-	5 working days	CDRRHR-RRD
3. Applicant upload the compliance documents from the noted deficiencies during inspection in the RRD portal.	3.1. Conducts pre-licensing inspection and upload inspection report in the RRD portal. *If compliant, application is recommended for the issuance of authorization. **If not, the assigned inspector shall notify the applicant of the lacking regulatory requirements. ***If the facility fails to comply within the prescribed period, a letter of disapproval shall be sent to the facility.	-	20 working days	CDRRHR-RRD Assigned Inspector

	3.2. Evaluates the compliance documents. *If compliant, application is recommended for the issuance of authorization. **If not, the evaluator shall notify the applicant of the lacking regulatory requirements. ***If the facility fails to comply within the prescribed period, a letter of disapproval shall be sent to the facility.		3 working days	CDRRHR-RRD Evaluator
	3.3. Reviews/ recommends the LTO/LOD for final approval/ disapproval to the center director.	-	7 working days	CDRRHR-RRD QA
	3.4. Approves/disapproves the LTO/LOD.	-	5 working days	CDRRHR Director
4. Download and print the issued LTO/LOD.		-	-	Applicant
	TOTAL:	Refer to Table of Fees Above	40 working days	

Please be advised that as per RA No.11032 IRR, page 22 of 48, Section 3, b) The maximum time prescribed in Section 9 (b) (1) of the Act may be extended only once for the same number of days, which shall be indicated in the Citizen's Charter.

Note: *The processing of LTO initial application is a multistage system which involves pre-licensing inspection or radiation protection survey and evaluation (RPSE) of radiation facilities.

**Day 1 commences upon posting of payment.

STEPS FOR RENEWAL APPLICATION OF LICENSE TO OPERATE (LTO), INITIAL/ RENEWAL APPLICATION OF CERTIFICATE OF FACILITY REGISTRATION (CFR)

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
1. Encode required fields in the on-line application and upload the documentary requirements.	1. Pre-assessment of the on-line applications and attached documents. *If complete, order of payment will be generated **If not, a system generated notification will be sent to the facility stating that the application is hereby denied.	-	-	CDRRHR-RRD Assessor
2. Download, print order of payment, pay the corresponding fee at the FDA recognized payment centers.	2.1. Validation and posting of payment.	Refer to Table of Fees Above	-	FDA Cashier
	2.2. Reviews/ recommends the LTO/CFR/LOD for final approval/ disapproval to the center director.	-	10 working days	CDRRHR-RRD QA
	2.3. Approves/ disapproves the LTO/CFR/LOD.	-	5 working days	CDRRHR Director
3. Download and print the issued LTO/CFR/LOD.		-	-	Applicant
	TOTAL:	Refer to Table of Fees Above	15 working days	
Please be advised that as per RA No.11032 IRR, page 22 of 48, Section 3, b) The maximum time prescribed in Section 9 (b) (1) of the Act may be extended only once for the same number of days, which shall be indicated in the Citizen's Charter. Note: **Day 1 commences upon posting of payment.				

STEPS FOR MINOR VARIATION APPLICATION OF LICENSE TO OPERATE (LTO) & CERTIFICATE OF FACILITY REGISTRATION (CFR)

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
1. Encode required fields in the on-line application and upload the documentary requirements.	1.1. Evaluation of the on-line applications and attached documents. *If complete application is recommended for the issuance of authorization. **If not, a system generated notification will be sent to the facility stating that the application is hereby denied.	-	5 working days days	CDRRHR-RRD Evaluator
	1.2. Reviews/ recommends the LTO/CFR/LOD for final approval/ disapproval to the center director.	-	5 working days	CDRRHR-RRD QA
	1.3. Approves/ disapproves the LTO/CFR/LOD.	-	5 working days	CDRRHR Director
2. Download and print the issued LTO/CFR/LOD.		-	-	Applicant
	TOTAL:	None	15 working days	
Please be advised that as per RA No.11032 IRR, page 22 of 48, Section 3, b) The maximum time prescribed in Section 9 (b) (1) of the Act may be extended only once for the same number of days, which shall be indicated in the Citizen's Charter.				

26.RE-APPLICATION FOR CMDR AND IVDR APPLICATIONS

The client's response or compliance to the issued Letter of Disapproval following their initial registration application. Clients are given 60 calendar days to comply from the date of the LoD issuance.

Center/Office/Division	:	CDRRHR-LRD
Classification	:	Highly Technical
Type of Transaction	:	G2B - Government-to-Businesses
Who May Avail	:	Medical Device Manufacturers/Distributors (Importer/Exporter/Wholesaler)/Trader
Fees to be Paid	:	Php 1,000.00 + 1% LRF = Php1,010.00

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
Letter of Intent	Applicant.
Copy of the Letter of Disapproval/Reapplication.	Applicant
Compliance Documents	Applicant/Principal/ Manufacturer
Payment	FDA Cashier
NOTES: Submit an electronic/scanned copy (in PDF searchable format of at least 150 dpi) The soft copy should be arranged according to the checklist of requirements. The file name should consist of the name of the requirement. The electronic copy should be contained either in one single continuous file per requirement or single continuous file for all requirements. Submission schedule applies to working days only and excludes national and declared non-working days. In the event of a holiday/non-working day, then the regular schedule shall be followed on the next working and scheduled submission day.	

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
Client sends an email containing the PDF of their compliance to fdac.pacd@fda.gov.ph within the prescribed time period stipulated in the Letter of Disapproval/Reapplication.*	1.1 Receiving officer sends an acknowledgment email to the client and assigns a new DTN to the application. FDAC forwards the re-application file to CDRRHR.	Php1,010	1 working day	FDAC Officer
	2 CDRRHR receives the re-application file and decks to the evaluator	None	1 working day	CDRRHR Administrative Staff
	3 Technical evaluation of application. Recommendation of Approval or Final Disapproval	None	10 working days	Technical Evaluator
	4 Quality Assurance - Checking of recommendation of the Supervisor	None	4 working days	LRD Chief
	5 Drafting and finalization of certificate/disapproval letter	None	1 working day	Technical Evaluator
	6 Final Approval/Disapproval and signature of the Director	None	1 working day	CDRRHR Director
	7 Scanning and transmittal of certificate/disapproval letter to the FDA Records Section	None	1 working day	CDRRHR Administrative Staff
	8 Queuing and endorsement to the FDA Releasing Section.	None	1 working day	AFS Records Officer / Administrative Officer
	TOTAL	P1,010.00	20 working days**	

*Submission period is within sixty (60) days from the issuance date of the Letter of Disapproval/Re-application.

**Service is covered under Republic Act No. 3720 Section 21 as amended by Executive Order No. 175 Section 13.

27.RE-APPLICATION FOR RENEWAL OF CMDR/CPR AND IVDR

The client's response or compliance to the issued Letter of Disapproval following their renewal application. Clients are given 30 calendar days to comply from the date of the LoD issuance.

Center/Office/Division	:	CDRRHR-LRD
Classification	:	Highly Technical
Type of Transaction	:	G2B - Government-to-Businesses
Who May Avail	:	Medical Device Manufacturers/Distributors (Importer/Exporter/Wholesaler)/Trader
Fees to be Paid	:	Php 1,000.00 + 1% LRF = Php1,010.00

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
Letter of Intent	Applicant
Copy of the Notice of Deficiencies	Applicant
Compliance Documents	Applicant / Principal/Manufacturer
Payment	FDA Cashier
NOTES: Submit an electronic/scanned copy (in PDF searchable format of at least 150 dpi) The soft copy should be arranged according to the checklist of requirements. The file name should consist of the name of the requirement. The electronic copy should be contained either in one single continuous file per requirement or single continuous file for all requirements. Submission schedule applies to working days only and excludes national and declared non-working days. In the event of a holiday/non-working day, then the regular schedule shall be followed on the next working and scheduled submission day.	

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
Client sends an email containing the PDF of their compliance to fdac.pacd@fda.gov.ph within the prescribed time period stipulated in the notice of deficiency.*	1.1 Receiving officer sends an acknowledgment email to the client and assigns a new DTN to the application. FDAC forwards the re-application file to CDRRHR.	Php1,010	1 working day	FDAC Officer
	2 CDRRHR receives the re-application file and decks to the evaluator	None	1 working day	CDRRHR Administrative Staff
	3 Technical evaluation of application. Recommendation of Approval or Final Disapproval	None	10 working days	Technical Evaluator
	4 Quality Assurance - Checking of recommendation of the Supervisor	None	4 working days	LRD Chief
	5 Drafting and finalization of certificate or disapproval letter	None	1 working day	Technical Evaluator
	6 Final Approval/Disapproval and signature of the Director	None	1 working day	CDRRHR Director
	7 Scanning and Transmittal of certificate or disapproval letter to the FDA Records Section.	None	1 working day	CDRRHR Administrative Staff
	8 Queuing and endorsement to the Releasing Section	None	1 working day	AFS Records Officer / Administrative Officer
	TOTAL	Php1,010.00	20 working days**	

*Submission period is within thirty (30) days from the issuance date of the Letter of Disapproval/Re-application.

**Service is covered under Republic Act No. 3720 Section 21 as amended by Executive Order No. 175 Section 13.

28.RENEWAL APPLICATION FOR CERTIFICATE OF PRODUCT REGISTRATION (CPR) FOR IN-VITRO DIAGNOSTIC DEVICES/REAGENTS (IVD)

The application for the renewal of CPR for IVD devices/reagents.

<table>
<tr><td>Center/Office/Division</td><td>:</td><td>CDRRHR-LRD</td></tr>
<tr><td>Classification</td><td>:</td><td>Highly technical</td></tr>
<tr><td>Type of Transaction</td><td>:</td><td>G2B - Government-to-Businesses</td></tr>
<tr><td>Who May Avail</td><td>:</td><td>Medical Device Manufacturers/Distributors (Importer/Exporter/Wholesaler)/Trader</td></tr>
<tr><td>Fees to be Paid</td><td>:</td><td>Php5,000.00 + 1% LRF for renewal with 5 years validity

Cost does not include the performance evaluation test; cost of testing depends on the corresponding National Reference Laboratory (NRL)

Late Renewal Fees (as per FDA Circular 2011-004)
<table>
<tr><th>Timeline (after expiry date of certificate)</th><th>Validity of certificate (in years)</th><th>Fee</th><th>Laboratory Fee (c/o NRL)</th><th>Surcharge</th><th>Penalty</th><th>LRF</th><th>Total</th></tr>
<tr><td>a. First month (10% penalty)</td><td>5</td><td>5,000.00</td><td></td><td>10,000.00</td><td>500.00</td><td>50.00</td><td>15550.00</td></tr>
<tr><td>b. 1st day of the second month (20% penalty)</td><td>5</td><td>5,000.00</td><td></td><td>10,000.00</td><td>1,000.00</td><td>50.00</td><td>16050.00</td></tr>
<tr><td>c. 1st day of the third month (30% penalty)</td><td>5</td><td>5,000.00</td><td></td><td>10,000.00</td><td>1,500.00</td><td>50.00</td><td>16550.00</td></tr>
</table>
</td></tr>
</table>

		d. 1st day of the fourth month (40% penalty	5	5,000.00		10,000.00	2,000.00	50.00	17050.00

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
1. Table of Contents with correct page number.	Applicant
Notarized Application Form Shall be completely filled-up; Model / Reference Number / Sizes / Codes shall be properly identified; Refrain from indicating the Brand name (if applicable) on the Name of the product and vice versa For kits/sets, identify the complete contents/inclusions on the space provided for device name; For multiple CPR schemes, an annex page may be attached. However, the product name and model / reference number / size/ code must be specified to which CPR it belongs to; For multiple models / reference number / size / codes, an annex page may be attached; The Product Registration Number must be indicated (RR/IVDR); Shall be signed by the proper authority as indicated on the form; Re-using forms is not acceptable since this is a legal document.	Applicant. Form may be downloaded on the FDA website
License to Operate (LTO) as a Medical Device Distributor (Importer/ Exporter/ Wholesaler)/ Local Manufacturer/Trader. Shall be valid The principal shall be reflected on the list of sources.	Applicant
Copy of the front and back pages of the latest Certificate of Product Registration	Applicant
Foreign Agency Agreement / Letter of Authorization. Shall be valid. Shall be authenticated/apostilled by the territorial Philippine Consulate. The product being applied must be indicated. For imported medical devices but the agreements are signed in the Philippines, it must be notarized locally, with passport ID page and record of arrival and departure of the principal to and from the Philippines of the signatory/ies, and must be signed by both parties.	Applicant or Principal/Source/Manufacturer

For open-dated agreements/authorizations, if the certificate is beyond the 5- year period, a re-issued agreement/authorization must be submitted or a notarized attestation by the Principal that the agreement/authorization is still in effect. For locally manufactured medical devices with exclusive distributor, the agreement should be duly notarized. For locally manufactured medical devices with toll manufacturer, agreement between the trader and the manufacturer should be duly notarized.	
Government issued a certificate attesting to the status of the Manufacturer with regard to the competence and reliability of the personnel and facilities, a Quality Systems Certificate of approval, or a compliance certificate for ISO 13485. Shall be valid Shall be authenticated/apostilled by the territorial Philippine Consulate For products that are manufactured in multiple sites or toll manufacturers, identify or highlight where the product will be sourced from. The product being applied must be indicated in the scope. For locally manufactured products, valid LTO of the manufacturer.	Principal/Source/Manufacturer
Real time stability test data and results which shall include: shelf life study in-use stability study Note : Shall be performed on at least three (3) different product lots.	Principal/Source/Manufacturer
Clear and readable photos of actual labeling materials Immediate label secondary packaging box label package insert/brochure. shall include blood sample collection and handling performance study results and summary cross reactivity and list of potential interfering substances (if applicable) warnings and precautions information of the manufacturer	Applicant

revision number	
For pregnancy test kit, 15 samples of the same lot with at least nine (9) months expiration date. NOTE: For other IVD applications, samples will be submitted directly to the respective NRLs. No. of samples required will depend on the requirement of each NRL.	Applicant
Evidence of registration fee/payment (charge slip/official receipt)	FDA Cashier
All documents shall be submitted in English language. Documents submitted in any other foreign language not accompanied by English Translation shall be disapproved. Submit an electronic/scanned copy (in PDF searchable format of at least 150 dpi) The soft copy should be arranged according to the checklist of requirements. The file name should consist of the name of the requirement. The electronic copy should be contained either in one single continuous file per requirement or single continuous file for all requirements. Schedule of submission will be generated by the FDA and sent through email to the client. Endorsement to the NRL depends on the schedule performance re-evaluation which will be indicated at the back of the certificate.	

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME*	PERSON RESPONSIBLE
Client sends an email containing the PDF of their application to	Receiving officer generates a Document Tracking Number	None		FDAC Officer

fdac.letters@fda.gov.ph following the correct schedule.	(DTN) and sends an acknowledgment email / order of payment to the client			
The applicant company receives the Order of Payment and pays the assessed fee through FDAC Cashier or any other means prescribed by FDA. (e.g. BANCNET, LANDBANK ONCOLL) The Order of Payment will only be valid for 24 hours.	2.FDA receives the payment from the applicant company for posting.	PHP5,050.00	Timeline starts after posting of payment	FDA Cashier
The applicant company receives the official receipt and sends the proof of payment to FDA Action Center (FDAC) through email	3.1 FDAC forwards the application to CDRRHR.	None	1 working day	FDAC Officer
	3.2 CDRRHR assigns the application to evaluator	None	1 working day	CDRRHR Administrative Staff
	3.3 The technical evaluator reviews the application. Recommends approval or disapproval. Includes endorsement to NRL if the product is scheduled for performance re-evaluation.	None	5 working days**	Technical Evaluator
	Performance Testing	c/o NRL	Timeline depends on the NRL procedure	c/o the National Reference Laboratory
	4 Review of Performance Evaluation report	None	2 working days	Technical Evaluator

	5 Quality Assurance - Checking of recommendation of the Supervisor	None	4 working days	LRD Chief
	6 Drafting and finalization of CPR.	None	2 working days	Technical Evaluator
	7 Final Approval/Disapproval and signature of the Director	None	1 working day	CDRRHR Director
	8 Transmittal to Records Section.	None	1 working day	CDRRHR Administrative Staff
	9 Scanning and barcoding of CPR. Queuing and endorsement to the FDA Releasing Section.	None	2 working days	AFS Records Officer / Administrative Officer
	TOTAL	PHP5,050.00	20 working days***	

*Day 1 commences upon the receipt of the proof of payment / posting of payment.

**Timeline provided is for applications that are complete and correct with no Notice of Deficiencies issued.

***Service is covered under Republic Act No. 3720 Section 21 as amended by Executive Order No. 175 Section 13.

29.TURNED INITIAL REGISTRATION OF CERTIFICATE OF PRODUCT REGISTRATION (CPR) FOR EQUIPMENT/DEVICES USED TO TREAT SHARPS, PATHOLOGICAL AND INFECTIOUS WASTES

The application for authorization issued for equipment and devices used to treat sharps, pathological and infectious wastes after the CPR has passed the certificate expiry date by 120 days and beyond.

<table>
<tr><td>Center/Office/Division</td><td>:</td><td>CDRRHR-LRD</td></tr>
<tr><td>Classification</td><td>:</td><td>Highly Technical</td></tr>
<tr><td>Type of Transaction</td><td>:</td><td>Government-to-Businesses</td></tr>
<tr><td>Who May Avail</td><td>:</td><td>Medical Device Manufacturers/Distributors (Importer/Exporter/Wholesaler)/Trader</td></tr>
<tr><td>Fees to be Paid</td><td>:</td><td>(4 Months and Above) – TURNED INITIAL
<table>
<tr><th>Manufacturers/ Distributors/ TSD Facility</th><th>Surcharge</th><th>Penalties 40%</th><th>Initial Fee</th><th>LRF 1%</th><th>Total</th></tr>
<tr><td>Below Php 1,000,000.00</td><td>6,000</td><td>2,000</td><td>5,000</td><td>50</td><td>Php13,050</td></tr>
<tr><td>Php 1,000,000 – Php 5,000,000</td><td>6,000</td><td>3,200</td><td>8,000</td><td>80</td><td>Php17,280</td></tr>
<tr><td>Above Php 5,000,000</td><td>6,000</td><td>4,000</td><td>10,000</td><td>100</td><td>Php20,100</td></tr>
<tr><td>Healthcare Waste Generators</td><td>4,000</td><td>1,200</td><td>3,000</td><td>30</td><td>Php8,230</td></tr>
</table></td></tr>
</table>

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
Properly and completely filled-up application form Must be signed by the company representative with date when signed Location of Installation shall be filled-up since the equipment will be inspected and tested for performance evaluation.	Applicant. Form may be downloaded from the FDA website.
Copy of issued CPR	Applicant
Copy of valid License to Operate (LTO)	Applicant

Copy of SEC Articles of Incorporation or DTI Certificate of Business Registration The activity of manufacturing, importing or distributing the equipment should be reflected in the Articles of Incorporation The DTI Certificate of Business Registration must be valid.	Applicant
Technology Approval from DOST-ITDI for new technologies	Applicant
Technical Report:	
6.1. Company profile;	Applicant
6.2. Characteristics and Sources of generated waste;	Applicant
6.3. Detailed description of treatment equipment to be tested including manufacturer's instructions and technical specifications;	Applicant
6.4. Operating procedures and conditions including as applicable treatment time, pressure, temperature, chemical concentration, doses, feed rates and waste load composition;	Applicant
6.5. Storage, handling and volume capacity;	Applicant
6.6. Applicable emission controls for suspected emissions;	Applicant
6.7. Potential hazards/toxicities of waste residues;	Applicant
6.8. Energy efficiency	Applicant
6.9. Occupational safety and health assurance.	Applicant
7. Copy of Operation Manual	Applicant
8. Layout / Plans	Applicant
8.1. Location of installation;	Applicant
8.2. Design / Drawing or picture of the device / equipment applied for;	Applicant
9. Supplementary requirements for equipment / devices used for chemical disinfection:	Applicant
9.1. Material Safety Data Sheet (MSDS) of the chemicals to be used for disinfection	Applicant
9.2. The chemical to be used should be registered with the DENR-EMB or must be compliant with the WHO guidelines for hazardous wastes.	Applicant

For healthcare waste generators (e.g. hospitals) and Treatment, Storage and Disposal (TSD) Facilities, the Environmental Compliance Certificate (ECC) issued by the Environmental Management Bureau-Department of Environment and Natural Resources (EMB-DENR) and the License to Operate issued by the Department of Health shall be submitted together with the above documentary requirements. - License to Operate should be valid.	Applicant
Notes: .This office shall not accept applications with incomplete requirements. .All documents should be submitted in electronic copy format. .All information contained in this application form will be held strictly confidential.	
*Submission schedule is every Thursday from 8:00 AM to 5:00 PM. This schedule applies to working days only and excludes national and declared non-working days. In the event of a holiday/non-working day, then the regular schedule shall be followed on the next working and scheduled submission day.	

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME*	PERSON RESPONSIBLE
Client sends an email containing the PDF of their application to cdrrhr-productregistration@fda.gov.ph following the correct schedule for application.	1 Receiving officer sends an acknowledgment email to the client and decks the application to the evaluator for pre-assessment.	None		CDRRHR Officer
	2 Pre-assessment and issuance of Order of Payment or Denial Letter.	None		Technical Evaluator
The applicant company receives the Order of Payment and pays the assessed fee through FDAC Cashier or any other means	2 FDA receives the payment from the applicant company for posting.	Refer Table Above	Timeline starts after posting of payment	FDA Cashier

prescribed by FDA. (e.g. BANCNET, LANDBANK ONCOLL). *The Order of Payment will only be valid for 3 working days.		Php13,050/ Php17,280/ Php20,100/ Php8,230		
The applicant company receives the official receipt and sends the proof of payment to cdrrhr-productregistration@fda.gov.ph through email.	1 CDRRHR assigns the application to an evaluator.	None	2 working days	CDRRHR Administrative Staff
.	2 Technical evaluation of application. Issuance of a Notice of Deficiencies or endorsement.	None	20 working days	Technical Evaluator
. Client complies with the Notice of Deficiencies *Clients are given 30 days to comply with the NOD. Non-compliance would mean disapproval of the application.	4.1 Evaluator reviews compliance documents.	None	10 working days	Technical Evaluator
	2 Once fully complied, endorsed to NRL for Performance Evaluation	None	1 working day	Technical Evaluator
.	Performance Testing	c/o NRL	Timeline depends on the NRL procedure	c/o EAMC-NRL
	3 Review of Performance Evaluation report	None	5 working days	Technical Evaluator
	4 Quality Assurance - Checking of recommendation of the Supervisor	None	5 working days	LRD Chief

	5 Drafting and finalization of CPR.	None	2 working days	CDRRHR Administrative Staff
	6 Final Approval/Disapproval and signature of the Director	None	1 working day	CDRRHR Director
	7 Assigning of number. Transmittal to the Records Section.	None	2 working days	CDRRHR Administrative Staff
	8 Scanning and barcoding of CPR. Queuing and endorsement to the FDA Releasing Section.	None	2 working days	AFS Records Officer / Administrative Officer
	TOTAL	Php17,280/ Php20,100/ Php8,230	50 working days**	

*Day 1 commences upon the receipt of the proof of payment / posting of payment.

**Service is covered under Republic Act No. 3720 Section 21 as amended by Executive Order No. 175 Section 13.

30.RENEWAL APPLICATION OF CERTIFICATE OF REGISTRATION FOR WATER PURIFICATION DEVICES/SYSTEM

The application for the renewal of CPR for water purification devices or systems.

<table>
<tr><td>Center/Office/Division</td><td>:</td><td>CDRRHR-LRD</td></tr>
<tr><td>Classification</td><td>:</td><td>Highly Technical</td></tr>
<tr><td>Type of Transaction</td><td>:</td><td>G2B - Government-to-Businesses</td></tr>
<tr><td>Who May Avail</td><td>:</td><td>Medical Device Manufacturers/Distributors (Importer/Exporter/Wholesaler)/Trader</td></tr>
<tr><td>Fees to be Paid</td><td>:</td><td>Water Treatment Devices: Php500.00 + Php10.00 LRF per product
Water Treatment System: Php1,000.00 + Php10.00 LRF per product

Late Renewal
(1 Day to 1 Month)

<table>
<tr><th></th><th>Surcharge</th><th>Penalties 10%</th><th>Renewal Fee</th><th>LRF</th><th>Total</th></tr>
<tr><td>Water Treatment Devices</td><td>1,000</td><td>50</td><td>500</td><td>10</td><td>Php1,560</td></tr>
<tr><td>Water Treatment System</td><td>2,000</td><td>100</td><td>1,000</td><td>10</td><td>Php3,110</td></tr>
</table>

(1 Month to 2 Months)

<table>
<tr><th></th><th>Surcharge</th><th>Penalties 20%</th><th>Renewal Fee</th><th>LRF</th><th>Total</th></tr>
<tr><td>Water Treatment Devices</td><td>1,000</td><td>100</td><td>500</td><td>10</td><td>Php1,610</td></tr>
<tr><td>Water Treatment System</td><td>2,000</td><td>200</td><td>1,000</td><td>10</td><td>Php3,210</td></tr>
</table>
</td></tr>
</table>

(2 Months to 3 Months)

	Surcharge	Penalties 30%	Renewal Fee	LRF	Total
Water Treatment Devices	1,000	150	500	10	Php1,660
Water Treatment System	2,000	300	1,000	10	Php3,310

(3 Months to 4 Months)

	Surcharge	Penalties 40%	Renewal Fee	LRF	Total
Water Treatment Devices	1,000	200	500	10	Php1,710
Water Treatment System	2,000	400	1,000	10	Php3,410

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
1. Properly and completely filled-up application form -Must be signed by the company representative with date when signed -Use the official and latest form	Applicant. Form may be downloaded from the FDA website.
2. Affidavit of Continuous Compliance -Use the official and latest form	Applicant

Bacteriological, physical and chemical test report from any laboratory accredited by the DOH. Bacteriological tests should include the following: HPC, Total Coliform and Fecal Coliform. For safe drinking water, the physical and chemical test results should consist of the following: color, odor, turbidity, total chloride, total hardness, pH, total dissolved solids, fluoride, nitrate, nitrite, sulfate, arsenic, cadmium, chromium, iron, lead and manganese. For purified water, the physical and chemical test results should consist of the following: color, odor, turbidity, total chloride, total hardness, pH, total dissolved solids, fluoride, nitrate, nitrite, sulfate, arsenic, cadmium, chromium, copper, iron, lead and manganese. The sampling for laboratory testing should be performed within two (2) months upon filing of renewal or the guidelines set forth in the latest version of Philippine National Standards for Drinking Water. For guidelines, refer to the latest version of the PNS for drinking water.	Applicant
4. Copy of old Certificate of Health-Related Device Registration -Include in the submission page 2 of old CPR and/or layout of the device	Applicant
5.Copy of valid License to Operate (LTO)	Applicant
*Performance evaluation testing is not required to be submitted given that the previous test results are still valid.	
NOTES: • Submit an electronic/scanned copy (in PDF searchable format of at least 150 dpi) • The soft copy should be arranged according to the checklist of requirements. The file name should consist of the name of the requirement. The electronic copy should be contained either in one single continuous file per requirement or single continuous file for all requirements. * Application should be filed two (2) months prior to the expiration of the validity of the CPR. Submission schedule is every Thursday from 8:00 AM to 5:00 PM. This schedule applies to working days only and excludes national and declared non-working days. In the event of a holiday/non-working day, then the regular schedule shall be followed on the next working and scheduled submission day.	

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME*	PERSON RESPONSIBLE
Client sends an email containing the PDF of their application to fdac.letters@fda.gov.ph following the correct schedule.	Receiving officer generates a Document Tracking Number (DTN) and sends an acknowledgment email / order of payment to the client.	None		FDAC Officer
The applicant company receives the Order of Payment and pays the assessed fee through FDAC Cashier or any other means prescribed by FDA. (e.g. BANCNET, LANDBANK ONCOLL) *The Order of Payment will only be valid for 24 Hours.	2 The FDA will receive the payment from the applicant company for posting.	See above table	Timeline starts after posting of payment	FDA Cashier
The applicant company receives the official receipt and sends the proof of payment to FDA Action Center (FDAC) through email	1 FDAC will forward the application to CDRRHR.	None	1 working day	FDAC Officer
	2 The CDRRHR will assign the application to evaluator	None	1 working day	CDRRHR Administrative Staff
	3 Technical evaluation of application. Issuance of a Notice of Deficiencies or endorsement.	None	5 working days	Technical Evaluator
Client complies with the Notice of Deficiencies *Clients are given 30 days to comply with the NOD. Non-compliance would mean disapproval of the application.	4.1 Evaluator reviews submitted compliance documents.	None	5 working days	Technical Evaluator
	2 Quality Assurance - Checking of recommendation of the Supervisor	None	2 working days	LRD Chief
	3 Drafting and finalization of CPR.		1 working day	CDRRHR Administrative Staff

	4 Final Approval/Disapproval and signature of the Director	None	1 working day	CDRRHR Director
	5 Assigning of number. Transmital to Records Section.	None	2 working days	CDRRHR Administrative Staff
	6 Scanning and Barcoding of CPR. Queuing and endorsement to the FDA Releasing Section.	None	2 working days	AFS Records Officer / Administrative Officer
	TOTAL	Php510.00/ Php1,010.00	20 working days**	

*Day 1 commences upon the receipt of the proof of payment / posting of payment.
**Service is covered under Republic Act No. 3720 Section 21 as amended by Executive Order No. 175 Section 13.

31.RENEWAL APPLICATION OF MEDICAL DEVICES FOR ALL CLASSIFICATIONS (CMDN FOR CLASS A AND CMDR FOR CLASS B, C, D)

The application for the renewal of CPR (CMDN and CMDR) for medical devices.

<table>
<tr><td>Center/Office/Division</td><td>:</td><td>CDRRHR-LRD</td></tr>
<tr><td>Classification</td><td>:</td><td>Highly Technical</td></tr>
<tr><td>Type of Transaction</td><td>:</td><td>G2B - Government-to-Businesses</td></tr>
<tr><td>Who May Avail</td><td>:</td><td>Medical Device Manufacturers/Distributors (Importer/Exporter/Wholesaler)/Trader</td></tr>
<tr><td>Fees to be Paid</td><td>:</td><td>Php5,000.00 + 1% LRF for renewal with 5-year validity (Php 5,050.00) per product

Late Renewal Fees (as per FDA Circular 2011-004)
<table>
<tr><th>Timeline (after expiry date of certificate)</th><th>Validity of certificate (in years)</th><th>Fee</th><th>Surcharge</th><th>Penalty</th><th>LRF</th><th>Total</th></tr>
<tr><td>a. First month (10% penalty)</td><td>5</td><td>5,000.00</td><td>10,000.00</td><td>500.00</td><td>50.00</td><td>15,550.00</td></tr>
<tr><td>b. 1st day of the second month (20% penalty)</td><td>5</td><td>5,000.00</td><td>10,000.00</td><td>1,000.00</td><td>50.00</td><td>16,050.00</td></tr>
<tr><td>c. 1st day of the third month (30% penalty)</td><td>5</td><td>5,000.00</td><td>10,000.00</td><td>1,500.00</td><td>50.00</td><td>16,550.00</td></tr>
<tr><td>d. 1st day of the fourth month (40% penalty)</td><td>5</td><td>5,000.00</td><td>10,000.00</td><td>2,000.00</td><td>50.00</td><td>17,050.00</td></tr>
</table></td></tr>
</table>

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
. Notarized Application Form Must be completely and accurately filled-up; Model / Reference Number / Sizes / Codes must be properly identified; For kits/sets, identify the complete contents/inclusions on the space provided for device name; LTO must be valid. However, if it is for renewal, submit proof of renewal application including the payment; For multiple CPR scheme, an annex page may be attached. However, the product name and model / reference number / size / code must be specified to which CPR it belongs to; For multiple models / reference number / size / codes, an annex page must be attached; For multiple models / reference number / size / codes, a Word copy must be submitted The Product Registration Number must be indicated (DVR/MDR/CMDN/CMDR); Should be signed by the proper authority as indicated on the form; Re-using forms is not acceptable.	Applicant. Form may be downloaded from the FDA website.
. Payment	FDA Cashier

. 1 Copy of Notarized Agreement / Letter of Authorization. Must be valid; The product being applied for must be indicated; For imported medical devices, with notarized declaration from the legal manufacturer or product owner attesting that the authorization / agreement is true and correct; For local agreements, it must be notarized locally, with passport ID page and record of arrival in the Philippines of the signatory/ies, and must be signed by both parties; The issuing party and the local market authorization holder must bear their approved name and address as indicated in the CPR; For open-dated agreements/authorizations, if the certificate is beyond the 5-year period, a certificate to confirm that the agreement is still valid must be submitted; Copy of the certificate shall be accompanied by a notarized declaration from the legal manufacturer or product owner attesting that the certificate is true and correct; For locally manufactured medical devices with exclusive distributors, the agreement should be duly notarized. For locally manufactured medical devices with toll manufacturer, agreement between the trader and the manufacturer should be duly notarized. For Imported Medical Devices - valid government-issued certificate attesting to the status of the manufacturer with regard to the competence and reliability of the personnel and facilities, a Quality Systems Certificate of approval, or a compliance certificate for ISO 13485. Copy of the certificate shall be accompanied by a notarized declaration from the legal manufacturer or product owner attesting that the certificate is true and correct; For products that are manufactured in multiple sites or toll manufacturers, identify or highlight where the product will be sourced from; The product being applied must be indicated in the scope. For locally manufactured medical devices, a valid LTO of the manufacturer must be submitted, a copy of valid ISO 13485 is also encouraged.	Principal/Source/Manufacturer
Colored picture of the device from all sides. However, the CDRRHR may require a representative sample or commercial presentation for verification purposes.	Principal/Source/Manufacturer

Must be removed from its packaging for clear visualization of the device.	
Clear and complete colored pictures of label from all sides of the packaging (loose label or artworks of all layers of packaging) Immediate label, secondary packaging, box label and package insert/brochure, whichever is applicable; All the approved product model / reference number / sizes / codes must be submitted, indicating both the international and mandatory labeling requirements; For any additional product claim/s on the label, submit studies or tests to support the claim/s; For imported products, if the brand name is the product's local brand, submit a declaration from the manufacturer allowing use of the brand name and its corresponding IPO approval; If the CE marking is reflected on the label, submit valid certificate supporting the placement of the CE mark; Labels must be legible even after when zoom in; Actual commercial labels must be submitted. Artworks are not acceptable since this is already for renewal; Primary packaging must be identified. All documents must be submitted in English language. Submit an electronic/scanned copy (in PDF searchable format of at least 150 dpi) The file name should consist of the name of the requirement.	Principal/Source/Manufacturer
Submit Table of Contents with correct page number.	

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME*	PERSON RESPONSIBLE
Client sends an email containing the PDF of their application to fdac.letters@fda.gov.ph following the correct schedule.	Receiving officer generates a Document Tracking Number (DTN) and sends an acknowledgment email / order of payment to the client.	None	Timeline starts after posting of payment	FDAC Officer
The applicant company receives the Order of Payment and pays the assessed fee through FDAC Cashier or any other means prescribed by FDA. (e.g. BANCNET, LANDBANK ONCOLL) The Order of Payment will only be valid for 24 hours.	FDA receives the payment from the applicant company for posting.	PHP5,050.00		FDA Cashier
The applicant company receives the official receipt and sends the proof of payment to FDA Action Center (FDAC) through email.	1 FDAC forwards the application to CDRRHR.	None		FDAC Officer
	2 CDRRHR assigns the application to evaluator.	None	1 Working day	CDRRHR Administrative Staff
	3 The technical evaluator reviews the application; Recommends approval or disapproval.	None	10 Working days**	Technical Evaluator

	4 Quality Assurance - Checking of recommendation of the Supervisor	None	4 working days	LRD Chief
	5 Drafting and finalization of CPR.		1 working day	Technical Evaluator
	6 Final Approval/Disapproval and signature of the Director.	None	1 working day	CDRRHR Director
	7 Assigning of number and printing of CMDN/CMDR. Transmittal of CMDN/CMDR to the Records Section.	None	2 working days	CDRRHR Administrative Staff
Pick-up of Certificate	Queuing and endorsement to the FDA Releasing Section.	None	1 working day	AFS Records Officer / Administrative Officer
	TOTAL	PHP5,050.00	20 working Days***	

*Day 1 commences upon the receipt of the proof of payment / posting of payment.
**Timeline provided is for applications that are complete and correct with no Notice of Deficiencies issued.
***Service is covered under Republic Act No. 3720 Section 21 as amended by Executive Order No. 175 Section 13.

32.TURNED INITIAL APPLICATION FOR CERTIFICATE OF MEDICAL DEVICE REGISTRATION (CMDR) FOR CLASS B

The application for authorization issued for medical devices that fall under Class B after the CPR has passed the certificate expiry date by 120 days and beyond.

Center/Office/Division	:	CDRRHR-LRD
Classification	:	Highly Technical
Type of Transaction	:	G2B - Government-to-Businesses
Who May Avail	:	Medical Device Manufacturers/Distributors (Importer/Exporter/Wholesaler)/Trader
Fees to be Paid	:	

APPLICATION	VALIDITY	FEE	SURCHARGE	PENALTY	LRF	TOTAL
Turned Initial (120 days after certificate's expiry date)	5 years	7,500.00	10,000.00	2,000.00	75.00	PHP19,575.00

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
Notarized Application Form Must be completely and correctly filled-up and signed Must use the latest form prescribed by the CDRRHR for the type of application Must submit one application form with attachment reflecting all the product codes being applied. Furthermore, the grouping of medical device family should be clearly specified. Only one condition should be considered in the multiple CPR application. Must be unedited, non-tampered; and must reflect the correct brand name, medical device name, and device risk-classification.	Applicant. Form may be downloaded from the FDA website.

1 copy of Notarized Agreement / Letter of Authorization. Must be valid; The product being applied must be indicated. For imported medical devices, with notarized declaration from the legal manufacturer or product owner attesting that the authorization / agreement is true and correct. For imported medical devices but the agreement is signed in the Philippines, it must be notarized locally, with passport ID page and record of arrival and departure of the principal to and from the Philippines of the signatory/ies, and must be signed by both parties. For open-dated agreements/authorizations, if the certificate is beyond the 5-year period from the document's issuance, a re-issued agreement/authorization or a notarized attestation by the Principal that the agreement/authorization is still in effect must be submitted. For locally manufactured medical devices with exclusive distributors, the agreement should be duly notarized. For locally manufactured medical devices with a toll manufacturer, the agreement between the trader and the manufacturer should be duly notarized.	Principal/Source/Manufacturer
For Imported Medical Devices - 1 copy of government-issued certificate attesting to the status of the Manufacturer with regard to the competence and reliability of the personnel and facilities, a Quality Systems Certificate of approval, or a compliance certificate for ISO 13485. Must be valid Copy of the certificate shall be accompanied by a notarized declaration from the legal manufacturer or product owner attesting that the certificate is true and correct. For products that are manufactured in multiple sites or toll manufacturers, identify or highlight the product source. The product being applied must be indicated in the scope. For locally manufactured products, submit the valid LTO of the manufacturer	Principal/Source/Manufacturer
For imported medical devices, 1 copy of Certificate of Product Registration, CE Certificate or any equivalent document attesting to the safety and effectiveness of the device issued by regulatory agency or accredited notified body in the country of origin. Must be valid The copy of the certificate shall be accompanied by a notarized declaration from the legal manufacturer or product owner attesting that the certificate is true and correct.	Principal/Source/Manufacturer

Clear colored picture of the actual commercial product sample of the device for all sides without its packaging, for all codes included in the application. An actual representative sample or commercial presentation can be required by the CDRRHR for verification purposes. Pictures should not be pixelated when the view is increased in size.	Principal/Source/Manufacturer
Technical Requirements	
Executive Summary. The executive summary shall include the following information: an overview, e.g., introductory descriptive information on the medical device, the intended uses and indications for use of the medical device, any novel features, and a synopsis of the content of the CSDT; the commercial marketing history; the list of regulatory approvals or marketing clearances obtained; the status of any pending request for market clearance; and the important safety/performance related information.	Applicant or Principal/Source/Manufacturer
Relevant essential principles and method/s used to demonstrate conformity. Must be completely filled-up	Principal/Source/Manufacturer

Device description with the following information: Intended use- this refers to the use for which the medical device is intended, for which it is suited according to the data supplied by the product owner in the instructions as well as the functional capability of the medical device. If the product is part of the system, the specific use of the product as part of the system should be indicated and not the intended use of the system. Indications of use- this is a general description of the disease or condition that the medical device will diagnose, treat, prevent, cure or mitigate; and includes a description of the target patient population for which the medical device is intended. Instruction for use- these are all necessary information from the product owner including the procedures, methods, frequency, duration, quantity and preparation to be followed for sale use of the medical device, instructions needed to use the medical device in a safe manner shall, to the extent possible, be included on the medical device itself and/or its packaging by other formats/forms. This is the detailed instruction for use for the users of the medical device. The instruction should be clear enough to guide its users. Contraindications- This is a general description of the disease or condition and the patient population for which the medical device should not be used for the purpose of diagnosing, treating, curing or mitigating. Contraindications are conditions under which the medical device should not be used because the risk of use clearly outweighs any possible benefit. Warnings-This is the specific hazard alert information that the user needs to know before using the medical device.	Principal/Source/Manufacturer

Precautions-This alerts the user to exercise special care necessary for the safe and effective use of the medical device. This may include actions to be taken to avoid effects on patients/users that may not be potentially life threatening or result in serious injury, but about which the user should be aware. Precautions may also alert the user to adverse effects on the medical device of use or misuse and the care necessary to avoid such effects. Potential adverse effects- These are potential undesirable and serious outcomes (death, injury, or serious adverse events) to the patient/user, or side effects from the use of the medical device, under normal conditions. Alternative therapy (practices and procedures) (if applicable) - This is a description of any alternative practices or procedures for diagnosing, treating, curing or mitigating the disease or condition for which the medical device is intended. Raw Materials or formulation. A description of the materials or formulation of the device and their physical properties to the extent necessary to demonstrate conformity with the relevant Essential Principles. The information shall include complete chemical, biological and physical characterization of the materials of the device. Should have a List of all raw materials used as a component of the product (specify for which product part or component the raw material is used) Must include quantity (for solutions) and technical specifications or detailed information on physical and chemical properties of each component. If the device contains PVC, identify the PVC plasticizer used. For kits/sets: submit the raw materials used with specifications of all components in the kit/set. For machines/equipment: The list of raw materials is ONLY required for the machine parts/accessories that: 1) will have a direct contact with the patient; and/or 2) will serve as a channel/conduit for medical gases during infusion (i.e. ventilators) - parts that come in direct contact with medical gases for infusion. Other Relevant Specifications to include the following:	

The functional characteristics and technical performance specifications of the device including, as relevant: accuracy, sensitivity, specificity of measuring and diagnostic medical devices, reliability, and other factors Other specifications including chemical, physical, electrical, mechanical, biological, software, sterility, stability, storage and transport, and packaging. May submit Certificate of Analysis or Test Certificate with finished product specification. For Stability, submit functionality and packaging/integrity test study of the product duly signed by the person who conducted the studies to justify the claimed expiration date. For accelerated study, submit computation to justify the storage conditions used. If no expiration, submit justification from the manufacturer why the device has no expiration. Submit in-use stability study, as applicable. (e.g. contact lens solution, disinfectant) Identify the product's storage condition. For products with special storage conditions, submit transport stability study. For packaging, clarify the type of packaging used. i.e. blister pack, carton box, etc. For medical devices with animal tissue origin, submit Certificate of Compliance with ISO 22442 - Medical devices utilizing animal tissues and their derivatives issued by Government Authority or notified body. Other Descriptive Information to demonstrate conformity with the relevant Essential Principles (e.g. biocompatibility category for the finished medical device)	

Summary of Design Verification and Validation Documents: The validation documents shall consist of the following: Declaration/Certificates of Conformity to the product standards issued by the manufacturer Summaries or reports of tests and evaluation based on other standards, manufacturer methods and tests, or alternative ways of demonstrating compliance covering the following appropriate tests reports and evaluations, whichever is applicable: a listing of and conclusions drawn from published reports that concern the safety and performance of aspects of the medical device with reference to the Essential Principles; Engineering test Laboratory test Biocompatibility test Animal Test Simulated Use software validation Pre-clinical studies The following standards shall be considered: Philippine National Standards (PNS), international standards (ISO, IEC) and other equivalent national standards (of these international standards). Philippine National Standard (PNS) ISO Standard or IEC Standard (whichever is applicable) in the absence of PNS. Standard developed by other International Standard Bodies recognized by the DOH, in the absence of PNS, ISO Standard, and IEC Standard. Any foreign standard that may be recognized by the DOH for the purpose of registration in the absence of PNS, ISO Standard, and IEC Standard, and standard developed by other International Standard Bodies recognized by the DOH.	Principal/Source/Manufacturer

Clear and complete colored pictures of label from all sides of the packaging (loose label or artworks of all layers of packaging) * Immediate label, secondary packaging, box label and package insert/brochure, whichever is applicable. For any additional product claims on the label, submit studies or tests supporting the claims. For imported products, if the brand name is the product's local brand, declaration from the manufacturer allowing use of the brand name and IPO approval of the said brand name. For local manufactured products, IPO approval of the-brand name If the CE marking is reflected on the label, submit a valid certificate supporting the placement of the CE mark. Pictures and text of the label should be clear and not be pixelated when the view is increased in size. Lot No., Batch No., Serial No., whichever is applicable, should be reflected. Expiration date, reference codes/sizes/variants/model whichever is applicable should be reflected. Storage condition, sterilization method should be reflected if applicable. Importer and distributor's name and address should be reflected in the label of the product together with the Registration Number. Suggested Retail Price (SRP) in Philippine peso. The above requirements shall be superseded upon the approval of Administrative Order for the labeling requirements for medical devices.	Applicant or Principal/Source/Manufacturer
Risk Analysis to include the results. Identify the risk Submit Failure Mode Effect Analysis / Risk Benefit Analysis	Principal/Source/Manufacturer

Physical Manufacturer information Manufacturing process, including quality assurance measures. This should include the manufacturing methods and procedures, manufacturing environment or conditions, facilities and controls. The information may be presented in the form of a process flow chart showing an overview of production, controls, assembly, final product testing, and packaging of finished medical device. A brief summary of the sterilization method should be included. Include sterilization standard parameters, sterilization procedures, validation protocol and results of latest sterilization revalidation. If the sterilization of the device is contracted out, submit a copy of valid ISO Certificate of the contracted sterilizing company. For non-sterile devices: a) submit Non-sterile declaration from the manufacturer; b) If the device is required to be sterilized prior to use, submit recommended sterilization guidelines from the manufacturer.	Principal/Source/Manufacturer
Payment	FDA Cashier
Documentary requirements must be arranged according to the CSDT format. All documents must be submitted in English language. Documents submitted in any other foreign language not accompanied by a notarized English translation for legal documents and an English translation for technical documents shall be disapproved. Documents to be uploaded should be in PDF searchable format of at least 150 dpi The file name to be uploaded should consist of the name of the requirements Provide table of contents with page number	

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME*	PERSON RESPONSIBLE
Client sends an email containing the PDF file of their application to cdrrhr-productregistration@fda.gov.ph following the correct schedule of application.	1 Receiving officer sends an acknowledgment email to the client and decks the application to the evaluator for pre-assessment.	None		CDRRHR Officer
	2 Pre-assessment and issuance of Order of Payment or Denial Letter.	None		CDRRHR Evaluator

The applicant company receives the Order of Payment and pays the assessed fee through FDAC Cashier or any other means prescribed by FDA. (e.g. BANCNET, LANDBANK ONCOLL). The Order of Payment will only be valid for 3 working days.	FDA receives the payment from the applicant company for posting	Php 7,575.00	Timeline starts after posting of payment	FDA Cashier
The applicant company receives the official receipt and sends the proof of payment to cdrrhr-productregistration@fda.gov.ph	1 CDRRHR assigns the application to evaluator	None	2 working days	CDRRHR Administrative Staff
	2 The technical evaluator reviews the application. Recommends approval or disapproval.	None	53 working days**	Technical Evaluator
	3 Quality Assurance - Checking of recommendation of the Supervisor	None	10 working days	LRD Chief
	4 Drafting and finalization of CPR.	None	3 working days	Technical Evaluator
	5 Final Approval/Disapproval and E-Signature	None	5 working days	CDRRHR Director
	6 Assigning of number and Printing of CMDR. Scanning, barcoding and transmitting of CMDR to the Records Section.		6 working days	CDRRHR Administrative Staff
	7 Queuing and endorsement to the FDA Releasing Section		1 working day	Administrative Officer
	TOTAL	Php 7,575.00	80 working days***	

*Day 1 commences upon the receipt of the proof of payment / posting of payment.

**Timeline provided is for applications that are complete and correct with no Notice of Deficiencies issued.

***Service is covered under Republic Act No. 3720 Section 21 as amended by Executive Order No. 175 Section 13.

33.TURNED INITIAL APPLICATION FOR CERTIFICATE OF MEDICAL DEVICE REGISTRATION (CMDR) FOR CLASS C AND D

The application for authorization issued for medical devices that fall under Class C or D after the CPR has passed the certificate expiry date by 120 days and beyond.

Center/Office/Division	:	CDRRHR-LRD
Classification	:	Highly Technical
Type of Transaction	:	G2B - Government-to-Businesses
Who May Avail	:	Medical Device Manufacturers/Distributors (Importer/Exporter/Wholesaler)/Trader
Fees to be Paid	:	

APPLICATION	VALIDITY	FEE	SURCHARGE	PENALTY	LRF	TOTAL
Turned Initial (120 days after certificate's expiry date)	5	7,500.00	10,000.00	2,000.00	75.00	19,575.00

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
Notarized Application Form Must be completely and correctly filled-up and signed Must use the latest form prescribed by the CDRRHR for the type of application Must submit one application form with attachment reflecting all the product codes being applied. Furthermore, the grouping of medical device family should be clearly specified. Only one condition should be considered in the multiple CPR application. Must be unedited, non-tampered; and must reflect the correct brand name, medical device name, and device risk-classification.	Applicant. Form may be downloaded from the FDA website.

1 Copy of Notarized Agreement / Letter of Authorization. Must be valid; For imported medical devices, with notarized declaration from the legal manufacturer or product owner attesting that the authorization / agreement is true and correct. For imported medical devices but the agreements are signed in the Philippines, it must be notarized locally, with passport ID page and record of arrival and departure of the principal to and from the Philippines of the signatory/ies, and must be signed by both parties. For open-dated agreements/authorizations, if the certificate is beyond the 5-year period from the document's issuance, a re-issued agreement/authorization or a notarized attestation by the Principal that the agreement/authorization is still in effect must be submitted. For locally manufactured medical devices with exclusive distributors, the agreement should be duly notarized. For locally manufactured medical devices with a toll manufacturer, the agreement between the trader and the manufacturer should be duly notarized.	Principal/Source/Manufacturer
For Imported Medical Devices - 1 copy of government-issued certificate attesting to the status of the Manufacturer with regard to the competence and reliability of the personnel and facilities, a Quality Systems Certificate of approval, or a compliance certificate for ISO 13485. Must be valid. Copy of the certificate shall be accompanied by a notarized declaration from the legal manufacturer or product owner attesting that the certificate is true and correct. For products that are manufactured in multiple sites or toll manufacturers, identify or highlight the product source. The product being applied must be indicated in the scope. For locally manufactured products, submit the valid LTO of the manufacturer.	Principal/Source/Manufacturer
For imported medical devices, 1 copy of Certificate of Product Registration, CE Certificate or any equivalent document attesting to the safety and effectiveness of the device issued by regulatory agency or accredited notified body in the country of origin. Must be valid. The copy of the certificate shall be accompanied by a notarized declaration from the legal manufacturer or product owner attesting that the certificate is true and correct. USA FDA 510K and PMA (Post Market Approval), Online registry from the Singapore HAS, and EC Full Quality Assurance and Design Verification Certificate	Principal/Source/Manufacturer

Clear colored picture of the actual commercial product sample of the device for all sides without its packaging, for all the codes included in the application. An actual representative sample or commercial presentation can be required by the CDRRHR for verification purposes. Pictures should not be pixelated when the view is increased in size.	Applicant or Principal/Source/Manufacturer
Technical Requirements	
Executive Summary. The executive summary shall include the following information: an overview, e.g., introductory descriptive information on the medical device, the intended uses and indications for use of the medical device, any novel features and a synopsis of the content of the CSDT; the commercial marketing history; the list of regulatory approvals or marketing clearances obtained; the status of any pending request for market clearance; and the important safety/performance related information.	Applicant or Principal/Source/Manufacturer
Relevant essential principles and method/s used to demonstrate conformity. Must be completely filled-up.	Principal/Source/Manufacturer
Device description with the following information: Intended use- this refers to the use for which the medical device is intended, for which it is suited according to the data supplied by the product owner in the instructions as well as the functional capability of the medical device. If the product is part of the system, the specific use of the product as part of the system should be indicated and not the intended use of the system. Indications of use- this is a general description of the disease or condition that the medical device will diagnose, treat, prevent, cure or mitigate and includes a description of the target patient population for which the medical device is intended. Instruction for use- this are all necessary information from the product owner including the procedures, methods, frequency, duration, quantity and preparation to be followed for sale use of the medical device, instructions needed to use the medical device in a safe manner shall, to the extent possible, be included on the medical device itself and/or its packaging by other formats/forms. This is the detailed instruction for use for the users of the medical device. The instruction should be clear enough to guide its users.	Principal/Source/Manufacturer

Contraindications- This is a general description of the disease or condition and the patient population for which the medical device should not be used for the purpose of diagnosing, treating, curing or mitigating. Contraindications are conditions under which the medical device should not be used because the risk of use clearly outweighs any possible benefit. Warnings-This is the specific hazard alert information that a user needs to know before using the medical device. Precautions-This alerts the user to exercise special care necessary for the safe and effective use of the medical device. They may include actions to be taken to avoid effects on patients/users that may not be potentially life threatening or result in serious injury, but about which the user should be aware. Precautions may also alert the user to adverse effects on the medical device of use or misuse and the care necessary to avoid such effects. Potential adverse effects- These are potential undesirable and serious outcomes (death, injury, or serious adverse events) to the patient/user, or side effects from the use of the medical device, under normal conditions. Alternative therapy (practices and procedures) (if applicable) - This is a description of any alternative practices or procedures for diagnosing, treating, curing or mitigating the disease or condition for which the medical device is intended. Raw Materials or formulation. A description of the materials or formulation of the device and their physical properties to the extent necessary to demonstrate conformity with the relevant Essential Principles. The information shall include complete chemical, biological and physical characterization of the materials of the device. Should have a List of all raw materials used as a component of the product (specify for which product part or component the raw material is used). Must include quantity (for solutions) and technical specifications or detailed information on physical and chemical properties of each component. If the device contains PVC, identify the PVC plasticizer used. For kits/sets: submit the raw materials used with specifications of all components in the kit/set.	

For machines/equipment: The list of raw materials is ONLY required for the machine parts/accessories that: 1) will have a direct contact with the patient; and/or 2) will serve as a channel/conduit for medical gases during infusion (i.e. ventilators) - parts that come in direct contact with medical gases for infusion. Other Relevant Specifications to include the following: j.1 The functional characteristics and technical performance specifications of the device including, as relevant: accuracy, sensitivity, specificity of measuring and diagnostic medical devices, reliability, and other factors j.2 Other specifications including chemical, physical, electrical, mechanical, biological, software, sterility, stability, storage and transport, and packaging. May submit Certificate of Analysis or Test Certificate with finished product specification. For Stability, submit functionality and packaging/integrity test study of the product duly signed by the person who conducted the studies to justify the claimed expiration date. For accelerated study, submit computation to justify the storage conditions used. If the product has no expiration, submit justification from the manufacturer why the device has no expiration. Submit in-use stability study, as applicable. (e.g. contact lens solution, disinfectant) Identify the product's storage condition. For products with special storage conditions, submit transport stability study. For packaging, clarify the type of packaging used. i.e. blister pack, carton box, etc. For medical devices with animal tissue origin, submit Certificate of Compliance with ISO 22442 - Medical devices utilizing animal tissues and their derivatives issued by Government Authority or notified body. Other Descriptive Information to demonstrate conformity with the relevant Essential Principles (e.g. biocompatibility category for the finished medical device)	

Summary of Design Verification and Validation Documents: The validation documents shall consist of the following: Declaration/Certificates of Conformity to the product standards issued by the manufacturer Summaries or reports of tests and evaluation based on other standards, manufacturer methods and tests, or alternative ways of demonstrating compliance, such as a listing of and conclusions drawn from published reports that concern the safety and performance of aspects of the medical device with reference to the Essential Principles; Data summaries or tests reports and evaluations covering the following appropriate test reports, whichever is applicable: Engineering test, including software validation studies, if applicable Laboratory test Biocompatibility test/biological evaluation Animal Test Simulated Use Clinical evidence Implantable devices Newly introduced devices Devices incorporating new materials coming into contact with the patient Existing materials applied in a body part not previously exposed to that material, and for which no prior chemical experience exists An existing device that is modified and the modification might affect the safety and effectiveness All other medical devices under Class D	Principal/Source/Manufacturer
Clinical evidence of the effectiveness may comprise of medical device-related investigations conducted domestically or other countries, or it may be derived from relevant publications in peer-reviewed scientific literature. The documented evidence submitted should include the objectives, methodology and results presented in context, clearly and meaningfully. The conclusions on the outcome of the clinical studies should be preceded by a discussion in context with the published literature.	

For Class D medical devices: A bibliography of all published reports dealing with the use, safety, and effectiveness of the device. Submit the most recent published reports for the medical device	
Clear and complete colored pictures of label from all sides of the packaging (loose label or artworks of all layers of packaging): Immediate label, secondary packaging, box label and package insert/brochure, whichever is applicable. For any additional product claims on the label, submit studies or tests supporting the claims. For imported products, if the brand name is the product's local brand, declaration from the manufacturer allowing use of the brand name and IPO approval of the said brand name. For local manufactured products, IPO approval of the said brand name If the CE marking is reflected on the label, submit a valid certificate supporting the placement of the CE mark. Pictures and text of the label should be clear and will not be pixelated when the view is increase in size Lot No., Batch No., Serial No., whichever is applicable should be reflected Expiration date, reference codes/sizes/variants/model whichever is applicable should be reflected Storage condition, sterilization method should be reflected if applicable Importer and distributor's name and address should be reflected in the label of the product together with the Registration Number. Suggested Retail Price (SRP) in Philippine peso. The above requirements shall be superseded upon the approval of Administrative Order for the labeling requirements for medical devices.	Applicant or Principal/Source/Manufacturer
Risk assessment which consists of risk analysis, evaluation and reduction measures. Identify the risk Submit Failure Mode Effect Analysis (FMEA) / Risk Benefit Analysis Evaluation of the effectiveness of control measures	Principal/Source/Manufacturer

Physical Manufacturer information: Manufacturing process, including quality assurance measures. This should include the manufacturing methods and procedures, manufacturing environment or conditions, facilities and controls. The information may be presented in the form of a process flow chart showing an overview of production, controls, assembly, final product testing, and packaging of finished medical device. A brief summary of the sterilization method should be included. Include sterilization standard parameters, sterilization procedures, validation protocol and results of latest sterilization revalidation. If the sterilization of the device is contracted out, submit copy of valid ISO Certificate of the contracted sterilizing company. For non-sterile devices: a) submit Non-sterile declaration from the manufacturer; b) If the device is required to be sterilized prior to use, submit recommended sterilization guidelines from the manufacturer.	Principal/Source/Manufacturer
Documentary requirements must be arranged according to the CSDT format. Submit an electronic/scanned copy (in PDF searchable format of at least 150 dpi) The soft copy should be arranged according to the checklist of requirements. The file name should consist of the name of the requirement. The electronic copy should be contained either in one single continuous file per requirement or single continuous file for all requirements. Provide table of contents with page number	

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME*	PERSON RESPONSIBLE
Client sends an email containing the PDF file of their application to cdrrhr-productregistration@fda.gov.ph following the correct schedule of application.	1 Receiving officer sends an acknowledgment email to the client and decks the application to the evaluator for pre-assessment.	None		CDRRHR officer
	2 Pre-assessment and issuance of Order of Payment or Denial Letter.	None		CDRRHR Evaluator
The applicant company receives the Order of Payment and pays the assessed fee through FDAC Cashier or any other means prescribed	FDA receives the payment from the applicant company for posting	PHP7,575.00	Timeline starts after posting of payment	FDA Cashier

by FDA. (e.g. BANCNET, LANDBANK ONCOLL). The Order of Payment will only be valid for 3 working days.				
The applicant company receives the official receipt and sends the proof of payment to cdrrhr-productregistration@fda.gov.ph through email.	1	CDRRHR assigns the application to evaluator	None	2 working days	CDRRHR Administrative Staff
	2	The technical evaluator reviews the application. Recommends approval or disapproval.	None	83 working days**	Technical Evaluator
	3	Quality Assurance - Checking of recommendation of the Supervisor	None	10 working days	LRD Chief
	4	Drafting and finalization of CPR.	None	3 working days	Technical Evaluator
	5	Final Approval/Disapproval and E-Signature	None	5 working days	CDRRHR Director
	6	Assigning of number and printing of CMDR. Scanning, barcoding, and transmitting of CMDR to the Records Section.	None	6 working days	CDRRHR Administrative Staff
	7	Queuing and endorsement to the FDA Releasing Section	None	1 working day	AFS Records Officer/ Administrative Officer
		TOTAL	PHP7,575.00	110 working days*** .	

*Day 1 commences upon the receipt of the proof of payment / posting of payment.

**Timeline provided is for applications that are complete and correct with no Notice of Deficiencies issued.

***Service is covered under Republic Act No. 3720 Section 21 as amended by Executive Order No. 175 Section 13.

34.TURNED INITIAL APPLICATION FOR CERTIFICATE OF PRODUCT REGISTRATION (CPR) FOR IN-VITRO DIAGNOSTIC DEVICES/REAGENTS (IVD)

The application for authorization issued for In Vitro Diagnostic Devices or Reagents after the CPR has passed the certificate expiry date by 120 days and beyond.

<table>
<tr><td>Center/Office/Division</td><td>:</td><td>CDRRHR-LRD</td></tr>
<tr><td>Classification</td><td>:</td><td>Highly technical</td></tr>
<tr><td>Type of Transaction</td><td>:</td><td>G2B - Government-to-Businesses</td></tr>
<tr><td>Who May Avail</td><td>:</td><td>Medical Device Manufacturers/Distributors (Importer/Exporter/Wholesaler)/Trader</td></tr>
<tr><td>Fees to be Paid</td><td>:</td><td>
<table>
<tr><th>APPLICATION</th><th>VALIDITY</th><th>FEE</th><th>LABORATORY FEE</th><th>SURCHARGE</th><th>PENALTY</th><th>LRF</th><th>TOTAL</th></tr>
<tr><td>Turned Initial (120 days after certificate’s expiry date)</td><td>1 year</td><td>1,500.00</td><td>c/o NRL</td><td>10,000.00</td><td>2,000.00</td><td>15.00</td><td>13,515.00</td></tr>
</table>
Additional Php1,000.00 + 1% LRF if the product is for the detection of hCG (pregnancy test) which requires performance evaluation testing

*Cost does not include the performance evaluation test; cost of testing depends on the corresponding National Reference Laboratory (NRL)
</td></tr>
</table>

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
1. Table of Contents with correct page number	Applicant
Notarized Application Form Must be completely filled-up; Model / Reference Number / Sizes / Codes must be properly identified; Refrain from indicating the Brand name (if applicable) on the Name of the product and vice versa For kits/sets, identify the complete contents/inclusions on the space provided for device name; For multiple models / reference number / size / codes, an annex page may be attached; For multiple models / reference number / size / codes; a Word copy must be submitted Should be signed by the proper authority as indicated on the form; Re-using forms is not acceptable since this is a legal document.	Applicant. Form may be downloaded from the FDA website.
License to Operate (LTO) as a Medical Device Distributor (Importer/ Exporter/ Wholesaler)/ Local Manufacturer/Trader. Shall be valid The principal shall be reflected on the list of sources.	Applicant
Government Certificate of Clearance and Free Sale/Registration approval from the country of origin issued by the Health Authority Shall be valid Shall be authenticated/apostilled by the territorial Philippine Consulate for Imported Product. For products with a trade name or reference code that differs per country, submit declaration or clarification from the manufacturer/principal. The product shall be stated on the list.	Principal/Source/ Manufacturer
For Imported Products - government issued certificate attesting to the status of the Manufacturer with regard to the competence and reliability of the personnel and facilities, a Quality Systems Certificate of approval, or a compliance certificate for ISO 13485. Shall be valid Shall be authenticated/apostilled by the territorial Philippine Consulate For products that are manufactured in multiple sites or toll manufacturers, identify or highlight where the product will be sourced from. The product being applied must be indicated in the scope. For locally manufactured products, valid LTO of the manufacturer	Principal/Source/ Manufacturer

Foreign Agency Agreement / Letter of Authorization. Shall be valid. Shall be authenticated/apostilled by the territorial Philippine Consulate. The product being applied must be indicated. For imported medical devices but the agreements are signed in the Philippines, it must be notarized locally, with passport ID page and record of arrival and departure of the principal to and from the Philippines of the signatory/ies, and must be signed by both parties. For open-dated agreements/authorizations, if the certificate is beyond the 5-year period, a re-issued agreement/authorization must be submitted or a notarized attestation by the Principal that the agreement/authorization is still in effect. For locally manufactured medical devices with exclusive distributors, the agreement should be duly notarized. For locally manufactured medical devices with toll manufacturer, agreement between the trader and the manufacturer should be duly notarized.	Applicant or Principal/Source/ Manufacturer
Technical Requirements	
Intended use and Directions for Use which includes the following Intended use - this refers to the use for which the medical device is intended, for which it is suited according to the data supplied by the product owner in the instructions as well as the functional capability of the medical device. If the product is part of the system, the specific use of the product as part of the system should be indicated and not the intended use of the system. Indications of use - this is a general description of the disease or condition that the medical device will diagnose, treat, prevent, cure or mitigate and includes a description of the target patient population for which the medical device is intended. Instruction for use - these are all necessary information from the product owner including the procedures, methods, frequency, duration, quantity and preparation to be followed for sale use of the medical device, instructions needed to use the medical device in a safe manner shall, to the extent possible, be included on the medical device itself and/or its packaging by other formats/forms. This is the detailed instruction for use for the users of the medical device. The instruction should be clear enough to guide its users.	Principal/Source/Manufacturer

Contraindications - This is a general description of the disease or condition and the patient population for which the medical device should not be used for the purpose of diagnosing, treating, curing or mitigating. Contraindications are conditions under which the medical device should not be used because the risk of use clearly outweighs any possible benefit. Warnings - This is the specific hazard alert information that a user needs to know before using the medical device. Precautions - This alerts the user to exercise special care necessary for the safe and effective use of the medical device. They may include actions to be taken to avoid effects on patients/users that may not be potentially life threatening or result in serious injury, but about which the user should be aware. Precautions may also alert the user to adverse effects on the medical device of use or misuse and the care necessary to avoid such effects. Potential adverse effects- These are potential undesirable and serious outcomes (death, injury, or serious adverse events) to the patient/user, or side effects from the use of the medical device, under normal conditions. Intended purpose, including the following information: Type of analyte or measure of the assay. Whether the test is quantitative or qualitative. Role of the test in the clinical use e.g. screening, diagnostic or detection, aid to diagnostic, monitoring. Disease or condition that the test is intended for. Type of specimen to be used e.g. serum, plasma etc. The intended users (e.g. Self-testing by lay person, near- patient by trained personnel or professionals). Assay type e.g. immunoassay, chemistry, cytochemistry, image analysis, immunohistochemistry. The specific name of the instrument required for the assay, if any. Test principle. Specimen type. Conditions for collection, handling, storage and preparation of the specimen. Reagent description and any limitation (e.g. use with a dedicated instrument only). Metrological traceability of values assigned to calibrators and trueness-control materials, including identification of applicable reference materials and/or reference measurement procedures of higher order. Assay procedure including calculations and interpretation of results. Information on interfering substances that may affect the performance of the assay. Performance characteristics (summarized analytical and diagnostic sensitivity, specificity, reproducibility, etc.) Reference intervals.	

Study design (population studies, N, type of sample, matrix, dilution, target concentrations, etc.).	
List of all raw materials used as components of the reagents/test kit Product part or component where the raw material is used shall be specified Must include quantity (for solutions) and technical specifications or detailed information on physical and chemical properties of each component. If the product contains PVC, identify the PVC plasticizer used. For kits/sets submit all raw materials and specifications used.	Principal/Source/Manufacturer
9. Technical specifications of the Finished Product	Principal/Source/ Manufacturer
. Analytical and clinical performance studies to support IVD performance claims: Specimen type (suitability, collection, storage and transport stability) Equivalence between specimen types Analytical performance characteristics accuracy trueness and bias precision (repeatability and reproducibility) Analytical sensitivity (limit of detection, detection of variants) Analytical specificity (interference and cross-reactivity) Measuring range of the assay Validation of assay cut-off Validation of assay reading time Complete performance study to justify all the claims on the package insert	Principal/Source/Manufacturer
. Brief description of the manufacturing procedure/flowchart which shall include the ff: methods used in the facility controls in the manufacture processing packaging process flowchart showing an overview of production	Principal/Source/Manufacturer

. Risk Analysis to include the results Identify the risk Submit Failure Mode Effect Analysis	Principal/Source/Manufacturer
. Stability test data and results which shall include: shelf life study in-use stability study shipping stability studies to justify claimed shelf life Note: - Shall be performed on at least three (3) different product lots. - For accelerated study, indicate storage conditions, duration of study and computation to justify the storage condition used.	Principal/Source/Manufacturer
. Labeling materials Immediate label secondary packaging box label package insert/brochure. shall include blood sample collection and handling performance study results and summary cross reactivity and list of potential interfering substances (if applicable) warnings and precautions information of the manufacturer revision number	Principal/Source/ Manufacturer
. For pregnancy test kits, 15 samples of the same lot with at least nine (9) months expiration date. NOTE: For other IVD applications, samples will be submitted directly to the respective NRLs. Number of samples required will depend on the requirement of each NRL. Take note that the labeling materials for all the samples should be complete and the same.	Applicant
16. Evidence of registration fee/payment (charge slip/official receipt)	FDA Cashier

All documents shall be submitted in English language. Documents submitted in any other foreign language not accompanied by English Translation shall be disapproved. Submit an electronic/scanned copy (in PDF searchable format of at least 150dpi). The soft copy shall be arranged according to the checklist of requirements. The file name shall consist of the name of the requirement. The electronic copy shall be contained either in one single continuous file per requirement or single continuous file for all requirements. Bring hard copy of the assessment slip. Submission schedule will be generated by the FDA and sent thru email to client	

CLIENT STEPS		AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME*	PERSON RESPONSIBLE
Client sends and email containing the PDF file of their application to cdrrhr-productregistration@fda.gov.ph following the correct schedule of application.	1	Receiving officer sends an acknowledgment email to the client and decks the application to the evaluator for pre-assessment.	None	Timeline starts after posting of payment	CDRRHR Officer
	2	Pre-assessment and issuance of Order of Payment or Denial Letter.	None		Technical Evaluator

The applicant company receives the Order of Payment and pays the assessed fee through FDAC Cashier or any other means prescribed by FDA. (e.g. BANCNET, LANDBANK ONCOLL) The Order of Payment will only be valid for 3 working days.	The FDA will receive the payment from the applicant company for posting	Php1,500.00 + 1% LRF for initial with 1-year validity* Additional Php1,000.00 + 1% LRF if the product is for the detection of hCG (pregnancy test) which requires performance evaluation testing. Cost does not include the performance evaluation test; cost of testing depends on the corresponding National Reference Laboratory (NRL).		FDA Cashier
The applicant company receives the official receipt and sends the proof of payment to cdrrhr-productregistration@fda.gov.ph through email.	1 The CDRRHR will assign the application to evaluator	None	1 working day	CDRRHR Administrative Staff
.	2 The technical evaluator reviews the application. Recommends approval or disapproval. Endorsement of the	None	81 working days**	Technical Evaluator

	application to NRL for performance evaluation.			
.	Performance Testing	c/o NRL	Timeline depends on the NRL Procedure	c/o the National Reference Laboratory
	3 Review of Performance Evaluation report	None	5 working days	Technical Evaluator
.	4 Quality Assurance - Checking of recommendation of the Supervisor	None	10 working days	LRD Chief
	5 Drafting and finalization of CPR.	None	2 working days	CDRRHR Administrative Staff
.	6 Final Approval /Disapproval and signature of the Director	None	2 working days	CDRRHR Director
	7 Transmittal to Records Section.	None	1 working day	CDRRHR Administrative Staff
	8 Scanning and Barcoding of CPR. Queuing and endorsement to the FDA Releasing Section.	None	3 working days	AFS Records Officer / Administrative Officer
	TOTAL	PHP1,515.00 For HCG pregnancy test kits – additional PHP1,010.00	105 working days***	

*Day 1 commences upon the receipt of the proof of payment / posting of payment.

**Timeline provided is for applications that are complete and correct with no Notice of Deficiencies issued.

***Service is covered under Republic Act No. 3720 Section 21 as amended by Executive Order No. 175 Section 13.

35.TURNED INITIAL REGISTRATION OF CERTIFICATE OF PRODUCT REGISTRATION (CPR) FOR EQUIPMENT/DEVICES USED TO TREAT SHARPS, PATHOLOGICAL AND INFECTIOUS WASTES

The application for authorization issued for equipment and devices used to treat sharps, pathological and infectious wastes after the CPR has passed the certificate expiry date by 120 days and beyond.

Center/Office/Division	:	CDRRHR-LRD
Classification	:	Highly Technical
Type of Transaction	:	Government-to-Businesses
Who May Avail	:	Medical Device Manufacturers/Distributors (Importer/Exporter/Wholesaler)/Trader
Fees to be Paid	:	(4 Months and Above) – TURNED INITIAL

Manufacturers/ Distributors/ TSD Facility	Surcharge	Penalties 40%	Initial Fee	LRF 1%	Total
Below Php 1,000,000.00	6,000	2,000	5,000	50	Php13,050
Php 1,000,000 – Php 5,000,000	6,000	3,200	8,000	80	Php17,280
Above Php 5,000,000	6,000	4,000	10,000	100	Php20,100
Healthcare Waste Generators	4,000	1,200	3,000	30	Php8,230

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
Properly and completely filled-up application form Must be signed by the company representative with date when signed Location of Installation shall be filled-up since the equipment will be inspected and tested for performance evaluation.	Applicant. Form may be downloaded from the FDA website.
Copy of issued CPR	Applicant
Copy of valid License to Operate (LTO)	Applicant

Copy of SEC Articles of Incorporation or DTI Certificate of Business Registration The activity of manufacturing, importing or distributing the equipment should be reflected in the Articles of Incorporation The DTI Certificate of Business Registration must be valid.	Applicant
Technology Approval from DOST-ITDI for new technologies	Applicant
Technical Report:	
6.1. Company profile;	Applicant
6.2. Characteristics and Sources of generated waste;	Applicant
6.3. Detailed description of treatment equipment to be tested including manufacturer's instructions and technical specifications;	Applicant
6.4. Operating procedures and conditions including as applicable treatment time, pressure, temperature, chemical concentration, doses, feed rates and waste load composition;	Applicant
6.5. Storage, handling and volume capacity;	Applicant
6.6. Applicable emission controls for suspected emissions;	Applicant
6.7. Potential hazards/toxicities of waste residues;	Applicant
6.8. Energy efficiency	Applicant
6.9. Occupational safety and health assurance.	Applicant
7. Copy of Operation Manual	Applicant
8. Layout / Plans	Applicant
8.1. Location of installation;	Applicant
8.2. Design / Drawing or picture of the device / equipment applied for;	Applicant
9. Supplementary requirements for equipment / devices used for chemical disinfection:	Applicant
9.1. Material Safety Data Sheet (MSDS) of the chemicals to be used for disinfection	Applicant
9.2. The chemical to be used should be registered with the DENR-EMB or must be compliant with the WHO guidelines for hazardous wastes.	Applicant

For healthcare waste generators (e.g. hospitals) and Treatment, Storage and Disposal (TSD) Facilities, the Environmental Compliance Certificate (ECC) issued by the Environmental Management Bureau-Department of Environment and Natural Resources (EMB-DENR) and the License to Operate issued by the Department of Health shall be submitted together with the above documentary requirements. - License to Operate should be valid.	Applicant
Notes: .This office shall not accept applications with incomplete requirements. .All documents should be submitted in electronic copy format. .All information contained in this application form will be held strictly confidential.	
*Submission schedule is every Thursday from 8:00 AM to 5:00 PM. This schedule applies to working days only and excludes national and declared non-working days. In the event of a holiday/non-working day, then the regular schedule shall be followed on the next working and scheduled submission day.	

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME*	PERSON RESPONSIBLE
Client sends an email containing the PDF of their application to cdrrhr-productregistration@fda.gov.ph following the correct schedule for application.	Receiving officer sends an acknowledgment email to the client and decks the application to the evaluator for pre-assessment.	None		CDRRHR Officer
	Pre-assessment and issuance of Order of Payment or Denial Letter.	None	Timeline starts after posting of payment	Technical Evaluator
The applicant company receives the Order of Payment and pays the assessed fee through FDAC Cashier or any other means prescribed by FDA. (e.g. BANCNET, LANDBANK ONCOLL). *The Order of Payment will only be valid for 3 working days.	2 FDA receives the payment from the applicant company for posting.	Refer Table Above Php13,050/ Php17,280/ Php20,100/ Php8,230		FDA Cashier

The applicant company receives the official receipt and sends the proof of payment to cdrrhr-productregistration@fda.gov.ph through email.	CDRRHR assigns the application to an evaluator.	None	2 working days	CDRRHR Administrative Staff
.	Technical evaluation of application. Issuance of a Notice of Deficiencies or endorsement.	None	20 working days	Technical Evaluator
Client complies with the Notice of Deficiencies *Clients are given 30 days to comply with the NOD. Non-compliance would mean disapproval of the application.	4.1 Evaluator reviews compliance documents.	None	10 working days	Technical Evaluator
	Once fully complied, endorsed to NRL for Performance Evaluation	None	1 working day	Technical Evaluator
.	Performance Testing	c/o NRL	Timeline depends on the NRL procedure	c/o EAMC-NRL
	Review of Performance Evaluation report	None	5 working days	Technical Evaluator
	Quality Assurance - Checking of recommendation of the Supervisor	None	5 working days	LRD Chief
	Drafting and finalization of CPR.	None	2 working days	CDRRHR Administrative Staff
	Final Approval/Disapproval and signature of the Director	None	1 working day	CDRRHR Director
	Assigning of number. Transmittal to the Records Section.	None	2 working days	CDRRHR Administrative Staff
	Scanning and barcoding of CPR. Queuing and endorsement to the FDA Releasing Section.	None	2 working days	AFS Records Officer / Administrative Officer
	TOTAL	Php17,280/ Php20,100/ Php8,230	50 working days**	

*Day 1 commences upon the receipt of the proof of payment / posting of payment.

**Service is covered under Republic Act No. 3720 Section 21 as amended by Executive Order No. 175 Section 13.

36.TURNED INITIAL REGISTRATION OF CERTIFICATE OF REGISTRATION FOR WATER PURIFICATION DEVICES/SYSTEM

The application for authorization issued for water purification devices or systems after the CPR has passed the certificate expiry date by 120 days and beyond.

<table>
<tr><td>Center/Office/Division</td><td>:</td><td>CDRRHR-LRD</td></tr>
<tr><td>Classification</td><td>:</td><td>Highly Technical</td></tr>
<tr><td>Type of Transaction</td><td>:</td><td>G2B - Government-to-Businesses</td></tr>
<tr><td>Who May Avail</td><td>:</td><td>Medical Device Manufacturers/Distributors (Importer/Exporter/Wholesaler)/Trader</td></tr>
<tr><td>Fees to be Paid</td><td>:</td><td>Note: For renewal applications that are filed 120 days after expiry date of certificate
<table>
<tr><th>Surcharge</th><th>Penalties 40%</th><th>Initial Fee</th><th>LRF</th><th>Total</th></tr>
<tr><td>1,000</td><td>200</td><td>500</td><td>10</td><td>Php1,710</td></tr>
<tr><td>2,000</td><td>400</td><td>1,000</td><td>10</td><td>Php3,410</td></tr>
</table>
</td></tr>
</table>

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
Properly and completely filled-up application form Must be signed by the company representative with a date when signed. Claims should only be either for safe drinking water or purified water. Claims such as alkaline, ionized, PI, oxygenated or energized are not acceptable. Latest form should be used.	Applicant. Form may be downloaded from the FDA website.

Copy of SEC Articles of Incorporation or DTI Certificate of Business Registration The activity of manufacturing, importing or distributing the device should be reflected in the Articles of Incorporation The DTI Certificate of Business Registration must be valid.	Applicant
Copy of Mayor's Permit Must be Valid Name and address in the Mayor's Permit should be the same in the application form	Applicant
4. Copy of Operation Manual	Applicant
- Name and model number of the device in the operation manual should be the same with the application form and label	
.Layout of devices or flowchart of treatment process. - The lay out or flowchart should show every stage how the water is being treated. Include a narrative description for every stage or step of the treatment process Submit a clear and colored photo of the device. .List of raw materials used as components of the water purification device/system. Should have a list of the component parts with the corresponding raw material used in the device. .Label/labelling/product insert of manufacturer's performance claim Should be clear and readable. Name of the product and model number in the label should be consistent with the name and model number in the application form and operation manual. Name and address of the manufacturer, importer and distributor should be reflected Provide provision for the registration number .For special claims, data from scientific research and laboratory analysis supporting and proving the claims of the manufacturer of the product	Applicant
0. Copy of valid License to Operate (LTO)	Applicant

NOTES: • Submit an electronic/scanned copy (in PDF searchable format of at least 150 dpi) • The soft copy should be arranged according to the checklist of requirements. The file name should consist of the name of the requirement. The electronic copy should be contained either in one single continuous file per requirement or single continuous file for all requirements.	
*Submission schedule is every Friday from 8:00 AM to 5:00 PM. This schedule applies to working days only and excludes national and declared non-working days. In the event of a holiday/non-working day, then the regular schedule shall be followed on the next working and scheduled submission day.	

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME*	PERSON RESPONSIBLE
Client sends an email containing their application to cdrrhr-productregistration@fda.gov.ph following the correct schedule of application.	1 Receiving officer sends an acknowledgment email to the client and decks the application to the evaluator for pre-assessment.	None	Timeline starts after posting of payment	CDRRHR Officer
	2 Pre-assessment and issuance of Order of Payment or Denial Letter.	None		Technical Evaluator
Payment of the approved application at the Cashier		See above table Php1,710/ Php3,410		Cashier
	1 Transmittal of applications to CDRRHR	None	1 working day	FDAC Officer
.	2 Decking of application	None	2 working days	Data Controller

	3 Technical evaluation of application. Issuance of a Notice of Deficiencies or endorsement.	None	20 working days	Technical Evaluator
Client complies with the Notice of Deficiencies *Clients are given 30 days to comply with the NOD. Non-compliance would mean disapproval of the application.	3.1 Evaluator reviews submitted compliance documents.	None	13 working days	Technical Evaluator
	2 Quality Assurance - Checking of recommendation of the Supervisor	None	5 working days	LRD Chief
	3 Drafting and finalization of CPR.	None	2 working days	Administrative Officer
	4 Final Approval/Disapproval and E-Signature	None	3 working days	CDRRHR Director
	5 Assigning of number. Transmital to Records Section.	None	2 working days	Administrative Officer
	6 Scanning and barcoding of CPR	None	1 working day	Records Section Officer
	7 Queuing and endorsement to the FDA Releasing Section	None	1 working day	Releasing Section Officer
	TOTAL	Php1,710/ Php3,410	50 working days**	

*Day 1 commences upon the receipt of the proof of payment / posting of payment.

**Service is covered under Republic Act No. 3720 Section 21 as amended by Executive Order No. 175 Section 13.