ADMINISTRATIVE ORDER
No. 2014 - ________________

SUBJECT: The New Documentary Requirements for the Registration of Medical Device Products

I. Rationale

The fast evolution of medical technology and the importance of medical devices in the health care delivery system have awakened the regulators to look more into the safety and effectiveness of these devices through regulation while facilitating trade among the ten member states of the Association of Southeast Asian Nations (ASEAN). Structured and regionally accepted technical requirements were developed by the ASEAN member states through the ASEAN Consultative Committee on Standards and Quality – Medical Device Product Working Group (ACCSQ-MDPWG). The development of the common submission dossier template (CSDT) was a concerted effort of all the member states taking into consideration the global technical requirements developed by the Global Harmonization Task Force.

The CSDT is a set of technical requirements for the registration of the medical device products agreed by the ten ASEAN member states. The Philippines is committed to align the regulatory guidelines with this set of technical requirements, thus the development of this administrative order.

II. Declaration of Policy

Pursuant to Republic Act No. 9711, the Food and Drug Administration Act of 2009, and its implementing rules and regulation, this Administrative Order is formulated to govern the new documentary requirements for the registration of medical device products.

III. Objective

The new documentary requirements are hereby promulgated to align the Philippine medical device regulatory requirements to the common submission dossier template as agreed upon by the ten (10) member countries under the ASEAN, as part of the ASEAN Medical Device Directive.

IV. Scope

The new documentary requirements shall apply to all medical devices to be sold, imported, exported, manufactured, and used in the Philippines, except in-vitro diagnostic and refurbished medical devices, for both of which separate Administrative Orders shall be issued.
V. Definition of Terms

For the purpose of this Administrative Order, the terms below shall be defined as follows:

1. Applicant – refers to a local establishment, either a manufacturer, trader, distributor/importer/exporter applying for CMDN, CMDL, and/or CMDR.

2. Center for Device Regulation, Radiation Health and Research (CDRRHR) – refers to the regulatory office under the Food and Drug Administration (FDA) of the Department of Health (DOH) that is in-charge of the regulation of medical devices in the Philippines.

3. Certificate of Medical Device Notification (CMDN) – refers to the authorization issued to a medical device that complies with all the requirements for Notification of a medical device. The CMDN is issued to medical devices that will fall under class A.

4. Certificate of Medical Device Registration (CMDR) – refers to the authorization issued to a medical device that complies with all the requirements for Registration of a medical device. The CMDR is issued to medical devices that fall under classes B, C, and D.

5. Certificate of Listing (CL) – refers to the authorization issued to a medical device that is intended for research, clinical trial, exhibit, donation, etc that is not intended for sale.

6. Common Submission Dossier Template (CSDT) - is a set of technical requirements agreed upon by the ten member countries of the ASEAN which shall govern the regulation of medical devices in the ASEAN.

7. Country of origin – refers to the country where the device is manufactured or where the device has been registered and/or has been issued a market approval prior to distribution in the Philippines.

8. Distributor/importer/exporter - means any establishment that imports or exports raw materials, active ingredients and/or finished products for its own use or for wholesale distribution to other establishments or outlets.

9. Distributor/wholesaler - means any establishment that procures raw materials, active ingredients and/or finished products from local establishments for local distribution on a wholesale basis.

10. Inspection – refers to the on-site validation of the facility, records and any other pertinent documents in the possession of a person or business that manufactures, distributes, stores or sells medical devices.

11. In-Vitro Diagnostic Medical Device – refers to any reagent, reagent product, calibrator, control material, kit, instrument, apparatus, equipment or system whether used alone or in combination, intended by the manufacturer to be used in-vitro for the examination of specimens, including blood and tissue donation, derived from the human body solely or principally for the purpose of providing information:
   a. concerning a physiological or pathological state; or
   b. concerning a congenital abnormality; or
   c. to determine the safety and compatibility with potential recipients; or
   d. to monitor therapeutic measures.
12. License to Operate (LTO) – refers to the authorization issued by the FDA to a person or establishment to operate as a manufacturer, trader, distributor/importer/exporter/wholesaler of medical devices.

13. Listing - is the process of seeking authorization to use medical device products for research, clinical trial, exhibit, donation, etc., that are not intended for sale.

14. Manufacturer – refers to an establishment engaged in any and all operations involved in the production of medical device including preparation, processing, compounding, formulating, filling, packing, repacking, altering, ornamenting, finishing and labeling with the end in view of its storage, sale or distribution.

15. Medical Device – mean any instrument, apparatus, implement, machine, appliance, implant, in vitro reagent and calibrator, software, material or other similar or related article:

   • intended by the manufacturer/product owner to be used, alone or in combination, for human beings for one or more of the specific purpose(s) of:-
      - diagnosis, prevention, monitoring, treatment or alleviation of disease,
      - diagnosis, monitoring, treatment, alleviation of or compensation for an injury, investigation, replacement, modification, or support of the anatomy or of a physiological process,
      - supporting or sustaining life,
      - control of conception,
      - disinfection of medical devices,
      - providing information for medical or diagnostic purposes by means of in vitro examination of specimens derived from the human body; and
   • which does not achieve its primary intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its intended function by such means,

15. Notification – is the process of seeking authorization to manufacture, import, export, sale and/or distribute Class A medical devices in the Philippines.

16. Person – refers to any individual, partnership, corporation, association and/or organization.

17. Product Standards – refers to medical device standards set, formulated, developed and/or established by any of the following:

   a. Bureau of Product Standards (Philippine National Standard),
   b. International Standardization Organization (ISO),
   c. International Electrotechnical Commission (IEC),
   d. Other International Standard Bodies recognized by the DOH

   or any foreign standards that may be recognized by the DOH for the purpose of registration.

18. Refurbished Medical Device – refers to a medical device that was previously owned and reconditioned for re-sale and meets the safety and performance parameters set by the manufacturer.

19. Registration – means the process of approval of an application to register medical device prior to engaging in the manufacture, importation, exportation, sale, offer for sale, distribution, transfer, and where applicable, the use, testing, promotion, advertisement, and/or sponsorship of
medical device products.

20. Safety – means that the product will not impose any danger, injury, damage or undesirable effect to a person at the preset condition intended for the use of the medical device.

21. Trader – means any establishment which is a registered owner of a medical device and procures the raw materials and packing components and provides the production monographs, quality control standards and procedures, but subcontract the manufacture of such product to a licensed manufacturer. In addition, a trader may also engage in the distribution and/or marketing of its products.

VI. Classification of Medical Devices

The classification system of medical devices in this Administrative Order shall follow the classification system as agreed by the Medical Device Product Working Group under the ASEAN Consultative Committee on Standards and Quality which is rule-based and according to the level of risk. The classification to be used shall be Class A, B, C, and D, where class A is the classification for the low risk medical devices and class D for the highest risk medical devices. The classification rules shall be based on the ASEAN Medical Device Directive. The CDRRHR shall issue a listing of medical devices per classification.

The CDRRHR shall be authorized to reclassify certain devices when the level of risk of the device is changed by a certain incident in the manufacture, distribution or use of the device upon proper consultation with the advisory committee set forth by the Philippine FDA and/or the ASEAN for this purpose.

VII. Policies

1. The applicant shall classify the device based on the list of medical devices per classification issued by the CDRRHR. If the product is not included in the list, the company shall classify the device based on the intended use and on the classification rules of the ASEAN Medical Device Directive. The CDRRHR shall verify the classification made by the applicant and shall reclassify the device if another classification is deemed to be more appropriate.

2. All medical devices under class A shall apply for notification of medical device product, while all medical devices under classes B to D shall apply for registration of medical device product.

3. An application shall be made separately per specific medical device. In case of the following conditions, only one application can be filed; however, separate product certification/s shall be issued:

- medical device with accessories that are intended to be sold separately,
- medical device manufactured in multiple manufacturing sites and shall co-exist in the market,
- medical device system where the use of one part of the system is needed to be used together with all or any part of the system
- medical devices with the same intended use and the same manufacturing process but differ in one or more raw materials
- medical devices with the same intended use and the same manufacturing process but differ in the design
- medical devices with the same raw materials but differ in types or shapes resulting in different specific intended use.

The registration fee for this type of application shall be equivalent to the total registration fee for all the individual products that will be registered.

The applicant shall follow the FDA Memorandum Circular no. 2013-001: Guidelines on the Submission of LTO and CPR application with electronic copy (e-copy) and its subsequent amendments and implementing guidelines.

4. The Notification Number or Registration Number shall be issued to the device with approved CMDN or CMDR.

5. The CMDN shall be valid for five (5) years as long as there is no change in the composition, packaging, process, and components of the device and shall be renewed every five (5) years after the initial approval. When the distributor/manufacturer of the device ceased the production or distribution of such device, the CDRRHR shall be informed in writing within thirty (30) calendar days.

6. The initial CMDR shall be valid for five (5) years and shall be renewed every five (5) years after the initial approval. The CDRRHR can require the revalidation of the CMDR anytime within the five (5) year validity period to ensure the continuous compliance of the applicant with the regulation.

7. Filing for the renewal of the certificates of registration or notification shall be accepted within ninety (90) calendar days prior to the expiry date of the CMDR or CMDN.

8. Applications for renewal of certificates of registration or notification filed after the validity date shall be imposed with corresponding penalty in accordance with the existing rules and regulations on fees and charges. An application for renewal filed after one hundred twenty (120) calendar days shall not be accepted and shall be considered as initial application. Medical devices with expired validity and whose application was turned into an initial application shall cease the selling of such device until such time that the certification of product registration is approved. The applicant can, however, opt to request the retention of the product registration/notification number.

9. Follow-up on the status of the application shall only be entertained after the date indicated on the company’s receiving copy. The status of the application shall be posted in the FDA website.

10. All applications with deficiencies in the submission shall be given a maximum of ninety (90) calendar days to comply. Only one time compliance shall be accepted. Applications with non-compliances shall be disapproved. A re-application can be submitted within sixty (60) calendar days after disapproval. However, if after the re-application, there is still a non-compliance, the application shall be considered disapproved. If no compliance document is received within the set compliance period, the application shall be automatically considered disapproved.

11. The list of all approved CMDRs and CMDNs shall be posted in the FDA website.

12. Medical devices strictly for research, clinical trial, exhibit, and/or donated brand new medical devices are exempted from Notification and Registration. However, the researcher, institution and/or user of such devices shall apply for a Certificate of Listing.
13. The CDRRHR reserves the right to ask for any other requirements not indicated in this Order but deemed necessary to support the reliability and authenticity of the submitted documents and safety of the medical device product; or that may arise based on the submitted compliance documents.

14. Disapproved applications shall be returned to the applicant. In case the applicant does not claim the disapproved applications within 90 calendar days, the application documents shall be destroyed and discarded.

15. An approved application issued a certificate of product registration number shall place in the label of the medical devices the following national labeling requirements prior to sale and distribution of the medical device products.

   a. Name and address of the importer
   b. Name and address of the distributor (if exclusive distributor)
   c. Certificate of Product Registration number

The national labeling requirements shall be placed in all layers of the packaging. It shall be placed in the label of the immediate packaging when sold individually to the product user and/or for over-the-counter (OTC) products. If the space of the label of the immediate packaging is limited, at least the certificate of product registration number shall be placed.

VIII. Documentary Requirements

A. The following are the requirements for the application for the Notification of medical devices under Class A.

   A.1 National Legal Requirements

   1.1 Notarized e-copy affidavit (Annex A)
   1.2 Notarized Application Form (Annex B)
   1.3 Photocopy of the valid License to Operate in the Philippines issued by FDA
   1.4 Proof of payment or order of payment
   1.5 For distributors, the Certificate of Agreement between the Manufacturer and Distributor regarding the device; for imported medical devices, the Certificate shall be duly authenticated by the territorial Philippine consulate
   1.6 Government certificate attesting to the status of the Manufacturer ‘s competency and reliability of the personnel and facilities or Quality Systems Certificate of approval or compliance certificate with ISO 9000 series or ISO 13485. For imported medical devices, the Certificate shall be duly authenticated by the territorial Philippine Consulate
   1.7 For imported medical devices, 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/accredited notified body in the country of origin and duly authenticated by the territorial Philippine Consulate. Free sales certificate shall not be accepted.
1.8 Representative sample or commercial presentation of the product, when needed, and a color picture of the device

A.2 Technical Requirements in accordance with the Common Submission Dossier Template of the ASEAN Medical Device Directive

2.1 Device description consisting of the following:
   a. Intended use
   b. Instruction for use
   c. List of all raw materials
   d. Technical specification of the finished product
   e. List of reference codes, sizes, colors, models and variance, whichever is applicable.

2.2 Sterilization method and sterility test done on the device.

2.3 Certificate of Conformity to the aspect of manufacture relating to metrology for devices with measuring functions.

2.4 Declaration of Conformity (self declaration by the manufacturer) with product standards, if applicable

2.5 Sample of labels on the device and its packaging and other labeling materials to be used for the device that includes user’s or instruction manuals.

2.6 Stability studies of the product to justify claimed shelf-life, if applicable

B. The following are the requirements for Initial Registration of medical devices under class B in accordance with the CSDT template:

B.1 National Legal Requirements

1.1 Notarized e-copy affidavit (Annex A)

1.2 Notarized Application Form (Annex C)

1.3 Photocopy of the valid License to Operate in the Philippines issued by FDA

1.4 Proof of payment or order of payment

1.5 For distributors,a Certificate of Agreement between the Manufacturer and Distributor regarding the device; for imported medical device, the Certificate shall be duly authenticated by the territorial Philippine consulate

1.6 Quality Systems Certificate of approval on Manufacturing or compliance certificate with ISO 9000 series or ISO 13485. For imported medical device, the Certificate shall be duly authenticated by the territorial Philippine Consulate.

1.7 For imported medical devices,a 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/accredited notified body in the country of origin and duly authenticated by the territorial Philippine Consulate

1.8 Representative sample or commercial presentation of the product, when needed, and colored picture of the device
B.2 Technical Requirements in accordance with the Common Submission Dossier Template of the ASEAN Medical Device Directive

2.1 Executive Summary

2.2 Relevant essential principles and method/s used to demonstrate conformity, if applicable. The evidence of conformity should indicate the specific document. (see Annex L)

2.3 Device description consisting of the following:

a. Intended use
b. Indications of use/Instruction of use
c. Contraindications
d. Warnings
e. Precautions
f. Potential adverse effects
g. Alternative therapy (practices and procedures)
h. Materials. A description of the materials 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.

i. 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

- If applicable, other specifications including chemical, physical, electrical, mechanical, biological, software, sterility, stability, storage and transport, and packaging.

j. Other Descriptive Information to demonstrate conformity with the relevant Essential Principles (e.g. biocompatibility category)

2.4 Summary of Design Verification and Validation Documents:

a. Validation documents consisting of the following:

- Declaration/Certificates of Conformity to the “recognized 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 any of the following appropriate test reports, whichever is applicable:
  - Engineering test
  - Laboratory test
  - Biocompatibility test
  - Animal Test
  - Simulated Use
  - Software Validation

• Pre-clinical studies
  
  b. Medical Device Labeling – Sample of labels and its packaging
  
  c. Risk Analysis to include the results, when applicable

B.3 Physical Manufacturer Information

3.1 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.

3.2 A brief summary of the sterilization method should be included.

C. The following are the requirements for initial registration of medical devices under class C.

1. All of the requirements of class B, except for number 6 of B.2 and pre-clinical studies

2. Risk assessment consisting of risk analysis, evaluation and reduction measures.

3. Clinical evidence for the following:

   a. Implantable devices
   
   b. Newly introduced devices
   
   c. Devices incorporating new materials coming into contact with the patient.
   
   d. Existing materials applied in a body part not previously exposed to that material, and for which no prior chemical experience exists.
   
   e. An existing device that is modified and the modification might affect safety and effectiveness.

4. Software validation studies, if applicable.

5. Biological evaluation, if applicable.

D. The following are the requirements for the initial registration of medical devices under class D.

1. All requirements for class C, except item number 3.

2. Clinical evidence

3. List of counties where the device has been sold.
4. A summary of all studies on which the manufacturer relies to ensure that the device meets the safety and effectiveness.

5. A bibliography of all published reports dealing with the use, safety, and effectiveness of the device.

6. Objective evidence (study) on biological safety of the device, if the device contains animal or human tissue or their derivatives.

E. The following are the requirements for the renewal of notification/registration of medical devices for all classifications.

1. Notarized e-copy affidavit (Annex A)

2. Notarized Application Form (Annex B or C)

3. Photocopy of the valid License to Operate in the Philippines issued by FDA.

4. Photocopy of previous CMDR.

5. Proof of payment or order of payment.

6. Quality Systems Certificate of approval or compliance certificate with ISO 9000 series or ISO 13485. For imported medical device, the Certificate shall be duly authenticated by the territorial Philippine Consulate.

7. For distributors, Certificate of Agreement between the Manufacturer and Distributor regarding the device involved. For imported medical device the Certificate shall be duly authenticated by the territorial Philippine consulate.

8. Sample of commercial labels and its packaging and other labeling materials use for the device that includes user’s or instruction manuals

9. Color picture of the product

F. The following are the requirements for the Certificate of Listing

1. Notarized Application Form (Annex D)

2. Notarized letter addressed to the Director, Center for Device Regulation, Radiation Health and Research, stating that the medical device will be used solely for personal use, research, analysis, exhibit, or is being donated by a certain organization and is not intended for sale. The letter should contain the following information:
   a. Complete list of the devices indicating the brand and the name of the manufacturer of the product
   b. Declaration that the organization will 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.
3. 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.

4. For a donated medical device, a certified true copy of the deed of donation and deed of acceptance.

5. Copy of bill of lading, proforma invoice, or official receipt of purchase.

6. Copy of SEC or DTI registration, when applicable. If for personal use, copy of proof of residence.

IX. Evaluation Process

The application shall be evaluated within one hundred eighty (180) days upon filing of the applications. All applications that do not comply with the technical requirements shall be notified through a letter and shall be given a one-time chance to correct the deficiencies within ninety (90) days. If the applicant still fails to comply with the requirements, he/she will be given a chance to re-apply, with a corresponding fee, and to submit the complete compliance documents within sixty (60) days. Failure to comply with the required documentation within the given period shall be a ground for disapproval of the application.

X. Issuance of Certificates

The certificate of medical device notification (CMDN), certificate of medical device registration (CMDR), and Certificate of Listing (CL) shall be issued by the CDRRHR upon the approval of the Center Director or his/her authorized representative, if the application is found to be meritorious; otherwise, the application shall be disapproved. The initial or renewed CMDN and CMDR shall be valid for five (5) years.

XI. Fees and Charges

The schedule of fees and charges shall follow the existing fees and charges for medical device registration issued by the Food and Drugs Administration.

XII. Implementation

This administrative order shall be implemented as follows:

1. The administrative guideline shall initially cover all registrable products listed in FDA Memorandum Circular No. 2014-005: Updated List of Medical Devices required to be registered prior to sale, distribution and use. The CDRRHR shall release the list of medical devices per classification based on the classification set forth in the ASEAN Medical Device Directive.

2. The coverage of registration shall be extended to all medical devices not indicated in the list of registrable medical devices by phases. The schedule of implementation shall be issued in separate memoranda. The phases are listed as follows:
   - Phase 1: Notification of Class A
   - Phase 2: Registration of Class D
• Phase 3: Registration of Class B and Class C

3. All medical device establishments, including medical device retailers, shall submit through on-line submission the complete list of medical devices that they distribute, manufacture, import, repack, re-label, and/or export within one (1) year upon the effectivity of this Guideline.

XIII. Sanctions

The following are the grounds for disapproval, cancellation, revocation and/or non-renewal of CMDNand CMDR:

1. The manufacture, sale, offering for sale or transfer of device that does not meet all the requirements of safety and effectiveness.

2. Misrepresentation or concealment of significant data or information about the product sought to be registered;

3. Alteration, mutilation, destruction, obliteration or removal of any part of labeling;

4. Medical device that has a biological, chemical or physical property that may cause an unacceptable health risk;

5. Submission of falsified document(s);

6. Alteration or falsification of issued CMDN or CMDR.

XIV Confidentiality of Information

Any officers and employees of CDRRHR shall not make public or use for their own personal gain any trade secret or proprietary information which they obtain or become familiar with during the course of their official duties. Any official caught shall be dealt with in accordance with the existing sanctions.

XV Repealing Clause

All administrative orders, rules and regulations and administrative issuances or parts thereof inconsistent with the provision of this order are hereby repealed or modified accordingly.

XVI Effectivity

This order shall take effect immediately after publication in a newspaper of general circulation. The implementation of the registration of medical devices following the new set of regulatory requirements shall be one (1) year upon the effectivity of this Administrative Order. However, medical device establishments may voluntarily submit earlier their application using the new set of requirements.

ENRIQUE T. ONA, MD
Secretary of Health
ANNEX A

ELECTRONIC COPY (E-Copy) AFFIDAVIT

REPUBLIC OF THE PHILIPPINES
PROVINCE OF _____________
MUNICIPALITY OF __________

I, Mr./Ms. ___________________________, of legal age, single/married), is the (position) _________ and
authorized representative of the company____________________ with registered business address
at______________________________, after being sworn in accordance with law, depose and say:

a. That in the application for a License to Operate(LTO)/Certificate of Product Registration(CPR), I hereby
submit the necessary requirements (hardcopy) prescribed by the Food and Drug Administration including
the electronic/scanned copy (soft copy) in PDF Searchable Format at least 300 dpi on a DVD-R;

b. That the attached electronic copy of the LTO/CPR application requirements/records/dossier is the exact
duplicate of the hardcopy submitted to FDA;

c. That under no circumstances shall I submit, copy/transfer any unauthorized files, codes, scripts (including
but not limited to viruses or worms), documents and information.

d. Further state that any discrepancy/prejudicial contents or willful misrepresentation on any of the data in the
electronic copy of the LTO/CPR application requirements/records against the hardcopy shall be a ground
for disapproval of the application and/or legal action for perjury against me or any of the responsible
person/s in our company/establishment.

e. That upon return of the hard copy, we shall keep the hard copy for 5 years and/or as long as the
establishment and/or the product remains active in the market and the hard copy shall be made available
for audit/retrieval as determined by the FDA.

I declare under oath that the foregoing statement composed of one (1) page is true, correct and complete to
the best of my knowledge and belief.

IN WITNESS WHEREOF, I have hereunto set my hand this day of _____________, 2013, in the
Municipality of _____________, Province of _____________, Philippines.

Respectfully submitted:

______________________________
SIGNATURE ABOVE PRINTED NAME

______________________________
DESIGNATION DATE

NOTARY PUBLIC

Doc. No._____________________
Book No._____________________
Page No._____________________
Series of_____________________

Subscribed and sworn to before me this ____ day of _______ 201____.
TO THE DIRECTOR
Center for Device Regulation,
Radiation Health, and Research
Food and Drug Administration
Department of Health

Sir/Madam:

In Accordance with R.A. 9711 and other related issuances, we wish to apply for the ( ) initial ( ) renewal notification of our product.

APPLICATION FOR MEDICAL DEVICE NOTIFICATION

| Device Name: |  |
| Model/Reference Number/Property Code/Item Code: |  |
| Intended Use of Device: |  |

Applicant’s Company Name:

| Address: |  |
| Tel No. | Fax, No. | E-mail address: |

Company President/General Manager:

Regulatory Officer:

Pharmacist (when the regulatory officer is not a Pharmacist):

| Legal Manufacturer(Product Owner): |  |
| Address: |  |
| Actual Manufacturer: |  |
| Address: |  |

We hereby certify that the foregoing information and all other data submitted in connection with this application are true and correct. We understand that the failure to report all required information or submission of false or misleading information is an offense punishable by law. We certify that we have examined the following statements and we attest to their accuracy:

1. The Current Good Manufacturing Practice Guidelines for Medical Device is applied in full in the manufacture of this product.
2. The manufacturing procedure is exactly as specified in the submitted manufacturing process.
3. The product covered by this declaration will not undergo any change in the formulation, size, reference number, use, manufacturer, manufacturing process, labeling or commercial presentation without prior approval of this office.

4. Each batch of the finished product is tested and certified to be fully compliant with the specifications in the accompanying documentation.

5. The person releasing the product for sale is an authorized and/or qualified person.

6. The procedures for control of the finished product have been validated.

7. The market authorization holder has a standard operating procedure for handling any adverse event related to the use of the device.

8. The market authorization holder has a standard operating procedure for handling product recalls.

9. All the documentation referred to in this application is available for review during comprehensive inspection of the establishment.

10. We shall change the brand name so submitted should the proper authority decides with finality that we have no right to appropriate and utilize the said brand name; and

11. We shall acknowledge and agree to indemnify and/or hold FDA free and harmless against any and all third party claims arising from the acceptance of such brand name of the product for registration with FDA.

12. The product covered by this declaration will not undergo any change in the ownership, registrant’s address/location, manufacturer, ingredients, formulation, size, reference number, use, manufacturing process (if applicable), labeling or commercial presentation, and packaging of the product covered by this certificate of notification without prior approval of this office.

13. We acknowledge and agree that in the event that there is an unauthorized change in the ownership, its address/location, manufacturer, ingredients, formulation, size, reference number, use, manufacturing process (if applicable), labeling or commercial presentation, and packaging of the product:
   i. CDRRHR may automatically suspend the LTO and/or CPR of the product;
   ii. We will voluntarily recall the product from the market; and
   iii. We will indemnify and/or hold CDRRHR free and harmless against any and all third party claims and/or actions pertaining to the above unauthorized change(s).

Regulatory Officer:                         Owner/General Manager:

SIGNATURE OVER PRINTED NAME             SIGNATURE OVER PRINTED NAME
Government ID Number:

Date Issued:                               Date Issued:
Place Issued                              Place Issued

SUBSCRIBED AND SWORN before me this ______ day of ______ affiant exhibiting to me his/her
Community Tax Certificate indicated above.

Doc. No. ______
Page No. ______
Book No. ______
Series of ______
ANNEX C

TO THE DIRECTOR
Center for Device Regulation, Radiation Health, and Research
Food and Drug Administration
Department of Health

Sir/Madam:

In Accordance with R.A. 9711 and other related issuance’s, we wish to apply for the ( ) initial ( ) renewal registration of our product.

APPLICATION FOR MEDICAL DEVICE REGISTRATION

| Device Name:                                      |
| Device Propriety/Brand Name:                     |
| Model/Reference Number/Property Code/Item Code:   |
| Classification                                   |
| Class B                                           |
| Class C                                           |
| Class D                                           |
| Device’s Intended Use:                           |
| Applicant’s Company Name:                        |
| Address:                                         |
| Tel No.                                          |
| Fax. No.                                         |
| E-mail address:                                  |
| Company Owner/General Manager:                   |
| Regulatory Officer:                              |
| Pharmacist (when the regulatory officer is not a Pharmacist): |
| Legal Manufacturer(Product Owner):                |
| Address:                                         |
| Actual Manufacturer:                             |
| Address:                                         |

We hereby certify that the foregoing information and all other data submitted in connection with this application are true and correct. I understand that the failure to report all required information or submission of false or misleading information is an offense punishable by law. We certify that we have examined the following statements and we attest to their accuracy:
1. The Current Good Manufacturing Practice Guidelines for Medical Device is applied in full in the manufacture of this product.

2. The manufacturing procedure is exactly as specified in the submitted manufacturing process.

3. Product covered by this declaration will not undergo any change in the formulation, size, reference number, use, manufacturer, manufacturing process, labeling or commercial presentation without prior approval of this office.

4. Each batch of the finished product is tested and certified to be fully compliant with the specifications in the accompanying documentation.

5. The person releasing the product for sale is an authorized and/or qualified person.

6. The procedures for control of the finished product have been validated.

7. The market authorization holder has a standard operating procedure for handling any adverse event related to the use of the device.

8. The market authorization holder has a standard operating procedure for handling product recalls.

9. All the documentation referred to in this application is available for review during comprehensive inspection of the establishment.

10. We shall change the brand name so submitted should the proper authority decides with finality that we have no right to appropriate and utilize said brand name; and

11. We shall acknowledge and agree to indemnify and/or hold FDA free and harmless against any and all third party claims arising from the acceptance of such brand name of the product for registration with FDA.

12. Product covered by this declaration will not undergo any change in the ownership, registrant’s address/location, manufacturer, ingredients, formulation, size, reference number, use, manufacturing process (if applicable), labeling or commercial presentation, and packaging of the product covered by this certificate of notification without prior approval of this office.

13. We acknowledge and agree that in the event that there is an unauthorized change in the ownership, its address/location, manufacturer, ingredients, formulation, size, reference number, use, manufacturing process (if applicable), labeling or commercial presentation, and packaging of the product:

   iv. CDRRHR may automatically suspend the LTO and/or CPR of the product

   v. We will voluntarily recall the product from the market; and

   vi. We will indemnify and/or hold CDRRHR free and harmless against any and all third party claims and/or actions pertaining to the above unauthorized change(s).

Regulatory Officer: 

SIGNATURE OVER PRINTED NAME

Government ID Number: 

Date Issued: 

Place Issued: 

Owner/General Manager: 

SIGNATURE OVER PRINTED NAME

Government ID Number: 

Date Issued: 

Place Issued: 

SUBSCRIBED AND SWORN before me this _________ day of _________ affiant exhibiting to me his/her government ID Number indicated above.
**ANNEX D**

**TO THE DIRECTOR**

Center for Device Regulation, Radiation Health, and Research
Food and Drug Administration
Department of Health

Sir/Madam:

In Accordance with R.A. 9711 and other related issuance’s, we wish to apply for the listing of our product.

---

**APPLICATION FOR MEDICAL DEVICE LISTING**

<table>
<thead>
<tr>
<th>Device Name:</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Device Propriety/Brand Name</td>
<td></td>
</tr>
<tr>
<td>Model/Reference Number/Property Code/Item Code</td>
<td></td>
</tr>
<tr>
<td>Classification:</td>
<td></td>
</tr>
<tr>
<td>Class A</td>
<td></td>
</tr>
<tr>
<td>Class B</td>
<td></td>
</tr>
<tr>
<td>Class C</td>
<td></td>
</tr>
<tr>
<td>Class D</td>
<td></td>
</tr>
<tr>
<td>Intended Use of Device:</td>
<td></td>
</tr>
</tbody>
</table>

**Applicant’s Company Name:**

**Address:**

**Tel No.**

**Fax. No.**

**E-mail address:**

**Company Owner/General Manager:**

**Regulatory Officer/Company Representative:**

**Legal Manufacturer(Product Owner):**

**Address:**

**Actual Manufacturer:**

**Address:**

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I hereby certify that the foregoing information and all other data submitted in connection with this application are true and correct. I understand that the failure to report all required information or submission of false or misleading information is an offense punishable by law.

**Regulatory Officer/Company Representative:**

**Signature Over Printed Name**

**Government ID Number:**

**Date Issued:**

**Place Issued**

---

**Owner/General Manager:**

**Signature Over Printed Name**

**Government ID Number:**

**Date Issued:**

**Place Issued**

---
SUBSCRIBED AND SWORN before me this __________ day of _________ affiant exhibiting to me his/her
government ID indicated above.