## ANNEX B

## Procedure for the Checking of the Application Status of the Initial Application of Certificate of Medical Device Notification

1. Start checking the application status by clicking the link provided in the FDA generated email.

= 附 Gmail		Q Search mail	71- 71-	0 🕸 🏼
Compose				1 af 165 < >
Inbox	95	fdadev@fda.gov.ph to me *	C 11:10 (2 minut	tes ago) 🛧 🕤 🗄
🛱 Starred		Dear Juan A. dela Cruz,		
( Snoozed		This is an auto generated email in reference to your submitted applic	ation. Please do not reply to this email as it will not be received.	
▷ Sent		This is not yet an Acknowledgment Receipt of your application. You w	ill receive an assessment result which will indicate if your application or requirem	ent/s is incomplete or
Drafts	3	incorrect. Should your application after assessment is found to be con	mplete you will receive an Order of Payment. Please check your email from time t	lo time.
✓ More		Your application reference number is FDA-3000000075584. You may registration/medical_device/status. Attached herewith is the summary	check the status online at <a href="http://eservices.demo.fda.gov/ph/applications/certificat">http://eservices.demo.fda.gov/ph/applications/certificat</a> details of your application.	e_product_
Labels	+	Should your application was assessed to be incomplete, or incorrect,	you have to apply again online and you will be issued another reference number	for pre-assessment again.
		Should you receive an order of payment, your application is complete soon as we have validated or verified your payment. Please use your	and need to make your payment within 7 working days. An Acknowledgement R application reference number when making inquiries or tracking the status of you	ecelpt will be emailed as ir application.
		Should you have any inquiries or concerns, you may also send us an	email at fdac@fda.gov.ph or contact us at (02)8857-1900 local 1000, (02)8842-5	635.
		Thank you,		
		Center for Device Regulation, Radiation Health, and Research		
		One attachment • Scanned by Gmail ③		@+
		Application_Sum		
		Application_Sum		

- a. Checking of the application status may also be accessed through the eServices webpage.
  - i. Access the online portal through <u>http://eservices.fda.gov.ph/</u> and click "Applications" found on the upper right corner of the eServices landing page.



ii. Click Product Notification.



iii. Click Medical Device.



iv. Click Certificate of Medical Device Notification.



v. Click Application Status.

Home / Applications / Product patilization	n / Madian Davies / Crada	
Home / Applications / House House	In / Medical Device / Childh	
Certificate of Medical I	Device Notification	
Application Status For establishments that handle devide products	Initial           Apply for a new Certificate of Medical Device Notification	
Application Status For establishments that handle device products	Initial Apply for a new Certificate of Medical Device Notification	

2. Type in the reference number. The reference number is provided in the FDA generated email response to the submitted application. Click "Submit" once the Reference Number has been provided. The applicant will receive a verification code through email.

eServices Portal		Home	Applications	Downloadables FAQs
Home / Applications / Product notification / Medi	cal Device / Cmdn / Status			
Application Status				
Reference Number	2 Verification Code		3	Application Status
• Enter the reference number in	ndicated in your application.			
* Reference Number	Reference Number e.g. FDA-1000000001234			
			Submit	

3. Type in the Verification Code and click "Submit".

Home / Applications / Product notification / Medical Device / Cmdn / Status  Application Status for FDA-30000000XXXX   Reference Number  Application Code  Application Code  Verification code has been sent to your email. Please check your email and enter the verification code	eServices Portal		Home Applications	Downloadables FAQs
Application Status for FDA-30000000XXXX   Reference Number  Application Code  Application Status  Application code has been sent to your email. Please check your email and enter the verification code.  Verification Code	Home / Applications / Product notification / Medi	ical Device / Cmdn / Status		
Reference Number     Verification Code     A verification code has been sent to your email. Please check your email and enter the verification code. Verification Code	Application Status for FDA	4-300000000XXXX		
Verification Code	Reference Number     A verification code has beer verification code.	Verification Code	3 rour email and enter the	Application Status
	Verification Code		1	
C Resend Verification Code Submit	C Resend Verification Code		Submit	

a. In case of any problems with the verification code, the applicant may secure a new verification code by clicking "Resend Verification Code".

eServices Portal	нс	ome <b>Applications</b> Downloadables FA
Home / Applications / Product notification /	Medical Device / Cmdn / Status	
Application Status for FE	DA-30000000XXXX	
Reference Number	2 Verification Code	Application Status
<ul> <li>A verification code has b verification code.</li> </ul>	een sent to your email. Please check your ema	all and enter the
Verification Code		
Resend Verification Code		Submit

4. The applicant will be prompted to the "Application Status" page. Information about the status of the application will be posted onto this page.

Home / Applica	tions / Product	notification / Medical Device / C			
	ce Number	2 ve	rification Code	3 Applic	cation Status
	Steps	Activity	Timestamp	Action	
	0	APPLICATION	10 August 2023 15:36:47	Application Details	
	2	DATA CONTROLLER	10 August 2023 15:37:08		
	3	PRE-ASSESSMENT	10 August 2023 15:42:08		

a. For approved application, the CMDN can be downloaded by clicking the "Certificate of Medical Device Notification" tab.

	2	DATA CONTROLLER	16 August 2023 10:14:57		
	3	PRE-ASSESSMENT	16 August 2023 10:16:30	Assessment Result	
	4	PAYMENT	16 August 2023 10:48:32	Crder of Payment	
	5	CHECKING	16 August 2023 10:49:07		
	6	APPROVAL	16 August 2023 10:50:00	Certificate of Medical Device Notification	
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b. For disapproved application, the denial letter can be downloaded by clicking "Denial Letter".

1 Reference	Number	2	Verification Code	3 App	ication Status
_	Steps	Activity	Timestamp	Action	
	1	APPROVAL	22 August 2023 13:05:26	Denial Letter	