

APPLICATION FORM FOR MEDICAL DEVICE NOTIFICATION

TO THE DIRECTOR GENERAL

Food and Drug Administration
Department of Health

ATTN: The Director
Center for Device Regulation, Radiation Health, and Research

Sir/Madam:

In accordance with R.A. 9711 and other related issuance/s, we wish to apply for the () initial () renewal **notification** of our product.

APPLICATION FOR MEDICAL DEVICE NOTIFICATION

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

Applicant's Company Name:	
Address:	
LTO No.	Validity:
Tel No.Fax. No.	E-mail address:
Company President/General Manager:	
Regulatory Officer:	

Legal Manufacturer (Product Owner):
Address:
Manufacturing site:

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/ Quality Management System (ISO) 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 finished product is tested and certified to be fully compliant with the specifications in the accompanying documentation.
4. The person releasing the product for sale is an authorized and/or qualified person.
5. The procedures for control of the finished product have been validated.
6. The applicant has a standard operating procedure for handling any adverse event related to the use of the device.
7. The applicant has a standard operating procedure for handling product recalls.
8. All the documentation referred to in this application is available for review during comprehensive inspection of the establishment.
9. 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
10. 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.
11. 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.
12. 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. The CDRRHR may automatically suspend the LTO and/or CMDN 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).
13. For abridged application, we attest that all of the product details including the CSDT technical documentation are exactly the same as the product details and CSDT technical documentation submitted in the ASEAN counterpart. In the event that there is an unauthorized change in the product details and CSDT documentation:
 - i. The CDRRHR may automatically suspend the LTO and/or CMDR of the product;
 - i. We will voluntarily recall the product from the market; and
 - ii. 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 issued ID Number:

Government issued ID Number:

Date Issued:

Date Issued:

Place of Issuance:

Place of Issuance:

SUBSCRIBED AND SWORN before me this _____ day of _____ affiant exhibiting to me his/her Government issued ID Number indicated above.

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