APPLICATION FORM FOR MEDICAL DEVICE REGISTRATION

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 registration of our product.

APPLICATION FOR MEDICAL DEVICE REGISTRATION

Type of Application: ☐ Initial ☐ Renewal ☐ Regular ☐ Abridged
Device Name:
Device Proprietary/Brand Name:
Model/Reference Number/Property Code/Item Code:
Classification: ☐ Class B ☐ Class C ☐ Class D Intended Use of Device:

Applicant's Company Name:
Address:
LTO No. Validity:
Tel No. Fax. No. E-mail address: Company Owner/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 decide 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 CMDR 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;
    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).
14. FDA reserves the right to forego abridged processing, as may be warranted, in case of any of following circumstances:
    i. Receipt of any negative report on the medical device from other countries;
    ii. When there are conflicting views or assessments from National Regulatory Authorities of other ASEAN countries on the same medical device; and
    iii. Other circumstances that may entail the FDA's careful evaluation of medical device applications for authorization.

Regulatory Officer:

SIGNATURE OVER PRINTED NAME
Government issued ID Number:

Date Issued:
Place of Issuance:

Owner/General Manager:

SIGNATURE OVER PRINTED NAME
Government issued ID Number:

Date Issued:
Place of Issuance:

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

NOTARY PUBLIC

Doc. No. _____
Page No. _____
Book No. _____
Series of _____