Republic of the Philippines
Department of Health
OFFICE OF THE SECRETARY

JAN 2 6 2018

ADMINISTRATIVE ORDER
No. ~~2017~~- 2018-0002

SUBJECT: Guidelines Governing the Issuance of an Authorization for a Medical Device based on the ASEAN Harmonized Technical Requirements

I. RATIONALE

The fast evolution of medical technology and the essential role of medical devices in the health care delivery system have highlighted the importance of ensuring 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 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 combined effort of the ASEAN 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 upon by the ten ASEAN member countries. The Philippines is committed to align its regulatory guidelines with this set of technical requirements, thus the issuance of this Administrative Order.

Pursuant to Republic Act No. 9711, the Food and Drug Administration (FDA) Act of 2009 and its implementing Rules and Regulations (IRR), this Administrative Order (AO) is being issued to govern the new sets of documentary requirements for the registration of medical device products.

II. OBJECTIVE

This Order aims to provide guidelines on the documentary requirements for the registration of medical devices and to align the registration requirements to the CSDT based on the provisions of the ASEAN Medical Device Directive.

III. 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 which separate Administrative Orders shall be issued.

IV. DEFINITION OF TERMS

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

1. **Applicant** – refers to any individual, partnership, corporation, association, and/or organization, either a manufacturer, trader, distributor/importer/ exporter applying for a CMDN, a CMDL, and/or a CMDR as defined below.

2. **Authorization** – refers to any certification issued to the applicant by CDRRHR showing the product has complied on documentary and technical requirements such as Notification and Registration with certificate.

3. **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.

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

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

6. **Certificate of Medical Device Listing (CMDL)** – refers to the authorization issued for a medical device that is intended for research, clinical trial, exhibit, donation, etc. and that is not intended for sale.

7. **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.

8. **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.

9. **Distributor/importer/exporter** - means any medical device 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.

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

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

    a. providing information concerning a physiological or pathological state; or
    b. providing information concerning a congenital abnormality; or
    c. determining the safety and compatibility with potential recipients; or
    d. monitoring therapeutic measures.

12. **Legal Manufacturer** –means any foreign medical device establishment with responsibility for the design, manufacture, packaging and labeling of a device before it is placed in the market under his own name, regardless of whether these operations are carried out by that person himself or on his behalf by a third party.

13. **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.

14. **Manufacturer** – refers to any medical device establishment engaged in any and all operations involved in the production of a 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** – means 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.

16. **Medical Device System** – is composed of different medical devices wherein each device is essential in the operation of the system.

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

18. **Product Owner** –in relation to a medical device, means any person who:
    a. supplies the medical device under his own name, or under any trade mark, design, trade name or other name or mark owned or controlled by him; and
    b. is responsible for designing, manufacturing, assembling, processing, labelling, packaging, refurbishing or modifying the medical device, or for assigning to it a purpose, whether those tasks are performed by him or on his behalf.

19. **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 Organization for Standardization (ISO),
    c. International Electrotechnical Commission (IEC),
    d. Other International Standard Bodies recognized by the DOH, or
    e. Any foreign standards that may be recognized by the DOH for the purpose of registration.

19. **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.

20. **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.

21. **Trader** – means any local establishment that is a registered product owner of a medical device, procures the raw materials and packing components, and provides the production monographs, quality control standards and procedures, but subcontracts 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.

V. GENERAL GUIDELINES

1. The classification system of medical devices in this Administrative Order shall follow the classification system as agreed on by the ACCSQ-MDPWG which is rule-based and according to the level of risk listed below:

Class	Risk Level
A	Low
B	Low-moderate
C	Moderate-high
D	High

A guidance document containing the list of medical devices per classification shall be issued. Reclassification of certain devices can be done when the level of risk of the device is changed by a certain incident in the manufacture, distribution or use of the device. This shall be done upon proper consultation with the advisory committee created by the Philippine FDA and/or the ASEAN for this purpose.

2. 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.

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

4. The Notification Number or Registration Number shall be issued to the device with an approved CMDN or CMDR. The CMDN and the CMDR shall be valid for five (5) years and shall be renewed every five (5) years after the initial approval.

5. The distributor/local manufacturer of the device shall inform the CDRRHR in writing within thirty (30) calendar days in case the distributor/local manufacturer has ceased the production or distribution of such device.

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

7. 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 Medical Device Listing.

8. 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.

9. 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.

VI. SPECIFIC GUIDELINES

1. An application shall be made separately for each specific medical device. In case of the following conditions, only one application can be filed; however, separate certificates of product registration shall be issued:

    a. a medical device with accessories wherein the accessories are intended to be sold separately,
    b. a medical device, owned by the same legal manufacturer, that is manufactured in different manufacturing plants and will be both distributed at the same time in the Philippine market,
    c. a 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,
    d. medical devices with the same intended use and the same manufacturing process but differ in one or more raw materials,
    e. medical devices with the same intended use and the same manufacturing process but differ in the design,
    f. medical devices with the same raw materials but differ in types or shapes resulting in different specific intended use.

2. The registration fee for application meeting the abovementioned condition/s shall be equivalent to the total registration fee for all the individual products that will be registered.

VII. PROCEDURAL GUIDELINES

A. Initial

1. All applications with deficiencies shall be given a one-time compliance period of a maximum of ninety (90) calendar days. If the deficiencies were not complied during the compliance period, the application shall be considered disapproved. However, the applicant may opt to submit a re-application within sixty (60) calendar days after the disapproval. If no compliance is received within the set compliance period, the application shall be automatically considered disapproved.

2. Product labels of the medical devices with issued CMDR or CMDN shall have the following national labeling requirements prior to sale and distribution:

    a. Name and address of the importer
    b. Name and address of the distributor (if exclusive distributor)
    c. CMDN number or CMDR number.

3. Documentary Requirements

    a. The list of requirements for the Notification of Class A medical devices & Registration of Classes B, C and D medical devices are as follows (attached as Annexes):

a.1 Annex A – Legal Requirements for Application for the Notification of Medical Devices under Class A and Registration of Medical Devices under Classes B, C and D

a.2 Annex B – Technical Requirements for Application for the Notification of Medical Devices under Class A

a.3 Annex C – Technical Requirements for the Initial Registration of Medical Devices under Class B in Accordance with the CSDT Template

a.4 Annex D – Technical Requirements for the Initial Registration of Medical Devices under Class C in Accordance with the CSDT Template

a.5 Annex E – Technical Requirements for the Initial Registration of Medical Devices under Class D in Accordance with the CSDT Template

b. The CDRRH reserves the right to ask for additional documents not indicated in this Order that may arise based on the submitted compliance documents

4. 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.

B. Renewal

1. The 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.

2. Applications for renewal of certificates of registration or notification filed after the validity date shall be fined with the corresponding penalty in accordance with the existing rules and regulations on fees and charges.

3. An application for renewal of CMDR filed after one hundred twenty (120) calendar days after its expiration shall not be accepted and shall be considered an initial application. The distribution and sale of that medical device shall automatically stop until such time that the certification of product registration have been approved. The applicant can opt, however, to request the retention of the product registration/notification number.

4. The application for renewal shall be evaluated within thirty (30) days upon filing of the application. 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 thirty (30) days.

5. The requirements for the renewal are attached as Annex F, Requirements for the Renewal of Notification/Registration of Medical Devices for all classifications.

C. Medical Device Listing

1. The filing of application for Medical Device Listing should be made prior to the importation of the medical devices.
2. The list of requirements for Medical Device Listing are attached as Annex G, Requirements for the Application of Medical Device Listing.

VIII. FEES AND CHARGES

The schedule of fees and charges shall follow DOH AO No. 50 s. 2001 and its amendments and revisions.

IX. PHASES OF IMPLEMENTATION

This AO shall cover initially 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" and its amendments; the Notification of all class A medical devices; and the Medical Device Listing. The CDRRHR shall release the list of medical devices per classification based on the classification set forth in the ASEAN Medical Device Directive.

The requirement of registration for all medical devices not indicated in the list of registrable medical devices shall be implemented in phases. The schedule of implementation shall be issued in separate memoranda. The phases are listed as follows:

1. Phase 1: Notification of Class B, C and D that are non-registrable medical devices based on FDA Memorandum Circular No. 2014-005.
2. Phase 2: Registration of Class D (Notification of Class D shall cease during this phase)
3. Phase 3: Registration of Class B and Class C (Notification of classes B and C shall cease during this phase)

X. SANCTIONS

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

1. The manufacture, sale, offer for sale, or transfer of a medical 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 a label;

4. A 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 an issued CMDN or CMDR.

The sanctions herein are in addition to the appropriate sanctions listed in the FDA Act of 2009 and its Implementing Rules and Regulations.

XI. MOTION FOR RECONSIDERATION/APPEAL

The procedure for the filing of Motion for Reconsideration or Appeal shall be in accordance with the provisions stipulated in Republic Act 9711 and its Implementing Rules and Regulations.

XII. 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 who violates this provision shall be dealt with in accordance with the Code of Conduct for Public Officials.

XIII. SEPARABILITY CLAUSE

If any portion or provision of this Order is declared invalid or unenforceable or unconstitutional, the validity or enforceability of the remaining portions or provisions shall not be affected, and this Order shall be construed as if it did not contain the particular invalid or enforceable or unconstitutional portion or provision.

XIV. REPEALING CLAUSE

FDA Memorandum Circular No. 2014-005, Updated List of Medical Devices required to be registered prior to sale distribution and use, and all other issuances inconsistent with the provision of this Order are hereby repealed or modified accordingly.

XV. EFFECTIVITY

This AO shall take effect fifteen (15) days following the completion of its publication in two (2) newspapers of general circulation and filing of three (3) copies hereof to the University of the Philippines Office of the National Administrative Register (UP ONAR).

The implementation of the registration of medical devices following the new set of regulatory requirements shall be one (1) year after the effectivity of this Administrative Order.

The CDRRHR may allow the voluntary submission of applications using the new set of requirements earlier than the indicated implementation of this guidelines.

FRANCISO T. DUQUE III, MD, MSc
Secretary of Health

ANNEX A

Legal Requirements for Application for the Notification of Medical Devices under Class A and Registration of Medical Devices under Classes B, C and D

1. Notarized Application Form (Annex G or H)
2. Payment
3. Copy of Letter of Authorization. For imported medical devices, the copy of the Letter of Authorization shall be accompanied by an original copy of a notarized declaration from the legal manufacturer or product owner attesting that the authorization is true and correct.
4. A 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. For imported medical devices, the copy of the certificate shall be accompanied by an original copy of a notarized declaration from the legal manufacturer or product owner attesting that the certificate is true and correct.
5. For imported medical devices, the Certificate of Product Notification, Certificate of Product Registration, or any equivalent document attesting to the safety and effectiveness of the device issued by the regulatory agency or accredited notified body in the country of origin. The copy of the certificate shall be accompanied by an original copy of a notarized declaration from the legal manufacturer or product owner attesting that the certificate is true and correct.
6. Colored picture of the device from all sides. However, the CDRRHR can require a representative sample or commercial presentation for verification purposes.

ANNEX B

Technical Requirements for Application for the Notification of Medical Devices under Class A

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. Certificate of Conformity (issued by government agency dealing with metrology) on the aspect of manufacture relating to metrology for devices with measuring functions, if applicable
3. Declaration of Conformity (self declaration by the manufacturer) with product standards, if applicable
4. Clear and complete colored pictures of label from all sides of the packaging (loose label or artworks of all layers of packaging)
5. Declaration of shelf life

ANNEX C

Technical Requirements for the Initial Registration of Medical Devices under Class B in Accordance with the CSDT Template

1. Executive Summary. The executive summary shall include the following information:
    a. 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;
    b. the commercial marketing history;
    c. the intended uses and indications in labeling;
    d. the list of regulatory approvals or marketing clearances obtained;
    e. the status of any pending request for market clearance; and
    f. the important safety/performance related information.
2. Relevant essential principles and method/s used to demonstrate conformity, if applicable. (See Annex K)
3. Device description with the following information:
    a. Intended Use
    b. Indications of use
    c. Instruction for use
    d. Contraindications
    e. Warnings
    f. Precautions
    g. Potential adverse effects
    h. Alternative therapy (practices and procedures)
    i. 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.
    j. 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 If applicable, other specifications including chemical, physical, electrical, mechanical, biological, software, sterility, stability, storage and transport, and packaging.
    k. Other Descriptive Information to demonstrate conformity with the relevant Essential Principles (e.g. biocompatibility category for the finished medical device)
4. Summary of Design Verification and Validation Documents:
    The validation documents shall consist of the following:
    a. Declaration/Certificates of Conformity to the product standards issued by the manufacturer
    b. 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;

c. Data summaries or tests reports and evaluations covering the following appropriate test reports, whichever is applicable:
    c.1 Engineering test
    c.2 Laboratory test
    c.3 Biocompatibility test
    c.4 Animal Test
    c.5 Simulated Use
    c.6 Software Validation
    c.7 Pre-clinical studies

5. Clear and complete colored pictures of label in all angles of the packaging (loose label or artworks of all layers of packaging)
6. Risk Analysis to include the results
7. Physical Manufacturer information
    a. 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.
    b. A brief summary of the sterilization method should be included.

ANNEX D

Technical Requirements for the Initial Registration of Medical Devices under Class C in Accordance with the CSDT Template

1. Executive Summary. The executive summary shall include the following information:
    a. 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;
    b. the commercial marketing history;
    c. the intended uses and indications in labeling;
    d. the list of regulatory approvals or marketing clearances obtained;
    e. the status of any pending request for market clearance; and
    f. the important safety/performance related information.
2. Relevant essential principles and method/s used to demonstrate conformity, if applicable. (See Annex K)
3. Device description with the following information:
    a. Intended use
    b. Indications of use
    c. Instruction for use
    d. Contraindications
    e. Warnings
    f. Precautions
    g. Potential adverse effects
    h. Alternative therapy (practices and procedures)
    i. 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.
    j. 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 If applicable, other specifications including chemical, physical, electrical, mechanical, biological, software, sterility, stability, storage and transport, and packaging.
    k. Other Descriptive Information to demonstrate conformity with the relevant Essential Principles (e.g. biocompatibility category for the finished medical device)
4. Summary of Design Verification and Validation Documents:
    The validation documents shall consist of the following:
    a. Declaration/Certificates of Conformity to the product standards issued by the manufacturer
    b. 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;

c. data summaries or tests reports and evaluations covering the following appropriate test reports, whichever is applicable:
    c.1 Engineering test
    c.2 Laboratory test
    c.3 Biocompatibility test
    c.4 Animal Test
    c.5 Simulated Use
d. Clinical evidence for the following:
    d.1 Implantable devices
    d.2 Newly introduced devices
    d.3 Devices incorporating new materials coming into contact with the patient.
    d.4 Existing materials applied in a body part not previously exposed to that material, and for which no prior chemical experience exists.
    d.5 An existing device that is modified and the modification might affect safety and effectiveness.
e. Software validation studies, if applicable.
f. Biological evaluation, if applicable.

5. Clear and complete colored pictures of label from all sides of the packaging (loose label or artworks of all layers of packaging)
6. Risk assessment consisting of risk analysis, evaluation and reduction measures.
7. Physical Manufacturer information
    a. 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.
    b. A brief summary of the sterilization method should be included.

ANNEX E

Technical Requirements for the Initial Registration of Medical Devices under Class D in Accordance with the CSDT

1. Executive Summary. The executive summary shall include the following information:
    a. 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;
    b. the commercial marketing history;
    c. the intended uses and indications in labeling;
    d. the list of regulatory approvals or marketing clearances obtained;
    e. the status of any pending request for market clearance; and
    f. the important safety/performance related information.
2. Relevant essential principles and method/s used to demonstrate conformity, if applicable. (See Annex K)
3. Device description with the following information:
    a. Intended use
    b. Indications of use
    c. Instruction for use
    d. Contraindications
    e. Warnings
    f. Precautions
    g. Potential adverse effects
    h. Alternative therapy (practices and procedures)
    i. 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.
    j. 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 If applicable, other specifications including chemical, physical, electrical, mechanical, biological, software, sterility, stability, storage and transport, and packaging.
    k. Other Descriptive Information to demonstrate conformity with the relevant Essential Principles (e.g. biocompatibility category for the finished medical device)
4. Summary of Design Verification and Validation Documents:
   The validation documents shall consist of the following:
    a. Declaration/Certificates of Conformity to the product standards issued by the manufacturer
    b. 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;

c. Data summaries or tests reports and evaluations covering the following appropriate test reports, whichever is applicable:
    - c.1 Engineering test
    - c.2 Laboratory test
    - c.3 Biocompatibility test
    - c.4 Animal Test
    - c.5 Simulated Use

d. Clinical evidence

e. Software validation studies, if applicable.

f. Biological evaluation, if applicable.

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

5. Clear and complete colored pictures of label from all sides of the packaging (loose label or artworks of all layers of packaging)
6. Risk assessment consisting of risk analysis, evaluation and reduction measures.
7. Physical Manufacturer information
    a. 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.
    b. A brief summary of the sterilization method should be included.

ANNEX F

Requirements for the Renewal of Notification/Registration of Medical Devices for All Classifications

1. Notarized Application Form (Annex H or I)
2. Payment
3. Copy of Letter of Authorization. For imported medical devices, the copy of the Letter of Authorization shall be accompanied by an original copy of a notarized declaration from the legal manufacturer or product owner attesting that the authorization is true and correct.
4. A 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. For imported medical devices, the copy of the certificate shall be accompanied by an original copy of a notarized declaration from the legal manufacturer or product owner attesting that the certificate is true and correct.
5. Colored picture of the device from all sides. However, the CDRRHR can require a representative sample or commercial presentation for verification purposes.
6. Clear and complete colored pictures of commercial label from all sides of the packaging.

ANNEX G

Requirements for Application for the Certificate of Medical Device Listing

1. Notarized Application Form (Annex J)
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 research, analysis, 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 quantity, brand and the name of the manufacturer of the product
    b. 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.

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 (brand new), a certified true copy of the deed of donation, the deed of acceptance, and the packing list or any document that will show the quantity of the product.

5. Copy of SEC or DTI registration, when applicable

ANNEX H: APPLICATION FORM FOR MEDICAL DEVICE NOTIFICATION (www.fda.gov.ph)

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).

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.

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ANNEX I: APPLICATION FORM FOR MEDICAL DEVICE REGISTRATION (www.fda.gov.ph)

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 **registration** of our product.

APPLICATION FOR MEDICAL DEVICE REGISTRATION

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).

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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ANNEX J: APPLICATION FORM FOR MEDICAL DEVICE LISTING (www.fda.gov.ph)

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 issuances, we wish to apply for the **listing** of our product.

APPLICATION FOR MEDICAL DEVICE LISTING

Device Name:
Device Proprietary/Brand Name:
Model/Reference Number/Property Code/Item Code:
Classification: ☐ Class A ☐ Class B ☐ Class C ☐ Class D
Intended Use of Device:

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: 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.

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:

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ANNEX K: EXAMPLE OF AN ESSENTIAL PRINCIPLES CONFORMITY CHECKLIST

Essential Principle	Applicable to the device?	Method of Conformity	Identity of Specific Documents
1. Medical devices should be designed and manufactured in such a way that, when used under the conditions and for the purposes intended and, where applicable, by virtue of the technical knowledge, experience, education or training of intended users, they will not compromise the clinical condition or the safety of patients, or the safety and health of users or, where applicable, other persons, provided that any risks which may be associated with their use constitute acceptable risks when weighed against the benefits to the patient and are compatible with a high level of protection of health and safety.	Yes		
2. The solutions adopted by the manufacturer for the design and construction of the devices should conform to safety principles, taking account of the generally acknowledged state of the art. In selecting the most appropriate solutions, the manufacturer should apply the following principles in the following order: • Identify hazards and the associated risks arising from the intended use and foreseeable misuse; • Eliminate or reduce risks as far as possible (inherently safe design and construction); • Where appropriate take adequate protection measures including alarms if necessary, in relation to risks that cannot be eliminated, • Inform users of the residual risks due to any shortcomings of the protection measures adopted.	Yes		
3. Devices should achieve the performance intended by the manufacturer and be designed, manufactured and packaged in such a way that they are suitable for one or more of the functions within the scope of the definition of a medical device applicable in each jurisdiction.	Yes		
4. The characteristics and performances referred to in Clauses 1, 2 and 3 should not be adversely affected to such a degree that the clinical conditions and safety of the patients and, where applicable, of other persons are compromised during the lifetime of the device, as indicated by the manufacturer, when the device is subjected to the stresses which can occur during normal conditions of use and has been properly maintained in accordance with the manufacturer's instructions.	Yes		
5. The devices should be designed, manufactured and packed in such a way that their characteristics and performances during their intended use will not be adversely affected during transport and storage taking account of the instructions and information provided by the manufacturer.	Yes		
7.1 The devices should be designed and manufactured in such a way as to ensure the characteristics and performance referred to in Section I of the "General Requirements". Particular attention should be paid to: • The choice of materials used, particularly as regards toxicity and, where appropriate, flammability, • The compatibility between the materials used and biological tissues, cells and body fluids, taking into account the intended purpose of the device. • The choice of materials used which should reflect, where appropriate, matters such as hardness, wear and fatigue strength.			
7.2 The devices should be designed, manufactured and packed in such a way as to minimize the risk posed by contaminants and residues to the persons involved in the transport, storage and use of the devices and to the patients, taking account of the intended purpose of the product. Particular attention should be paid to the tissues exposed and to the duration and frequency of exposure			