• PAMDRAP 23rd GMM 2022

MEDICAL DEVICE REGULATORY UPDATE

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Via Zoom

TOPICS:

- What's new?
- What's up?
- What's your Question?

What's new?

• LTO

License to Operate as Retailer is sill on pilot testing in Metro Manila. We encourage all retailers located in Metro Manila to apply for the LTO as this will help us check on the system to determine if there are still some more adjustments that need to be done

• ON RELIANCE

FDA Advisory 2021-3084

Applied to all **ASEAN Member Countries** with issued CPR equivalent following the **CSDT Technical Requirements based on AMDD**

Draft Guidelines:

Abridged Processing of Application for Registration/Notification of Medical Devices Approved by the Regulatory Authority of Any ASEAN Member Country

Final draft routed to concern FDA Offices on 25 May 2022 for clearance

What's up?

Type of Issuance	TITLE	STATUS
AO	Adoption of the Post Marketing Alert System (PMAS) Requirements, Annex 5 of the ASEAN Medical Device Directive (AMDD)	Final draft forwarded to ODG on 12 May 2022 for approval of final draft and for signature of endorsement to DOH
FDA Circular	Banning of all Mercury-Containing Thermometers, Sphygmomanometers, Dental Amalgam Capsules and Liquid Mercury for Use in Dental Restorative Purposes	Final draft forwarded to ODG on 13 May 2022 for approval of final draft and for signature of endorsement to DOH
AO	Rules and Regulations Governing the Issuance of an Authorization for an In-Vitro Diagnostic Medical Device (IVD)	As of 24 May 2022, for updating of the draft AO based the comments of the LSSC on certain legal issues on terminologies and requirements

Type of Issuance	TITLE	STATUS
FDA Circular	Specific List of Registrable In Vitro Diagnostic Medical Devices (IVDs) and Revised Technical Requirements for Registration of COVID-19 Test Kits	As of 24 May 2022, awaiting feedback from NKTI regarding concerns on testing done by NKTI
FDA Circular	Requirements for the Issuance of a Special Certification for Emerging New In Vitro Diagnostic Medical Devices Used for Detection and Diagnosis of SARS-CoV-2 Infection	Comments received during the virtual public hearing on 18 April 2022 for discussion within CDRRHR
FDA Circular	Good Storage and Distribution Practices for Medical Devices	For public hearing on 31 May 2022
AO	Revised Guidelines Governing the Issuance of an Authorization for a Medical Device based on the ASEAN Harmonized Technical Requirements	As of 24 May 2022, for updating of the draft AO based the comments of the LSSC on certain legal issues on terminologies and requirements

Type of Issuance	TITLE	STATUS
FDA Circular	Guidelines on the Labelling Requirements for Medical Devices in the Philippines	As per instruction: The issuance shall be changed into an FDA Circular and will wait for the amendment of AO 2018-0002 or the "Revised Guidelines Governing the Issuance of an Authorization for a Medical Device based on the ASEAN Harmonized Technical Requirements"
AO	Guidelines on the Conduct of Clinical Investigation of Medical Devices for Human Subjects in the Philippines	Awaiting Copies of PNS from DTI-BPS for ISO 14155:2020 (Clinical investigation of medical devices for human subjects — Good clinical practice) and ISO 20916:2019 (In vitro diagnostic medical devices — Clinical performance studies using specimens from human subjects — Good study practice) for inclusion in the draft guidelines

What's your Question?

On ONLINE FORM

1. ASEAN Medical Device Directive

a. Clarify the declared classification of the device based on ASEAN Medical Device Directive.

b. The manufacturer classified the product as Class I. However, the evaluator classified the product as Class B.

2. Accessories registration as part of the system

a. The accessories included in the machine/configuration depend on the hospital's order/requirements. Do we need to have 1 CMDN per configuration? Or can we put all possible configurations in one CMDN application?

b. Accessories that are part of the system, that are registrable, can we include that in the application?

c. Accessories that are not registrable like ECG cables, probes and part of CMDN license - can we import as standalone using the CMDN license of the host device? The accessories that will be imported (as replacement or consummable) will be used in the same host device.

d. For those accessories that are universal to different device, will CDRRHR require a separate standalone CMDN license?

e. Accessories to register with main device - is this only for those classified as medical device?

3. Groupings/Models

a. May I ask if anyone of you are also having similar issues on getting CMDN approval for Class B device per grouping/family? I tried to apply one CMDN for, let say, 10 reference codes of similar intended use but slightly differ in design. However, the FDA evaluator rejected the application and suggested to apply each code separately.. hoping for your feedback on this matter.

b. Can we have 1 CMDN application, different models? How about for CMDR, can we do it as 1 application?

c. Can we have one CMDN for different model if they differ only in size but same intended use/technical specs?

4. Software

a. When applying for machine softwares, do we need to apply separately? Or will the software be part of the machine submission?

b. Do you we need to indicate the software version in our CMDN application?

On LEGAL ISSUES

1. Notarized Declaration

a. Will an authenticated CCPIT be accepted in lieu of the notarize declaration letter?

b. For those countries that don't notarize, Is red ribbon/Apostille still acceptable?

c. Our supplier is a subsidiary of the main manufacturer. Then the supplier has a separate physical manufacturer. Who will issue the declaration of authenticity?

2. ISO Certificate

Is there an alternative document for GMP or ISO 13485 Certificate?

3. Certificate of Product Registration

a. Are CFG AND FSC accepted as proof of registration?

b. Is EC Certificate still acceptable as proof of registration/CPR? I got a denial the EC Certificate was not accepted by the evaluator.

c. Are CPR and CE mark acceptable even if it did not come from the country of origin? Our product's country of origin is Germany but due to MDD to MDR migration, some products lost their CE mark. Are we allowed to use CE issued from USA even if it's not the country of origin?

d. For those with CMDN license, can we also submit CMDN license as proof of registration when we submit for another CMDN (like diff manufacturing site)?

---------- Product certification ---------- ------ Quality system assessment -------

93/42/EEC Medical Devices (MDD)						
Type of certificate ⇨	EC Type-Examination Certificate	Certificate of Conformity	EC Design-Examination Certificate	EC Certificate Full Quality Assurance System	EC Certificate Production Quality Assurance	EC Certificate Product Quality Assurance
Module ⇨ Annex ⇨ **Class** ⇩	**Module B** III	**Module F** IV	**Module H** II (4)	**Module H** II excluding (4)	**Module D** V (3)	**Module E** VI (3)
Class I						
Class I Sterile		(F)		H3	D2	(E)
Class I measuring function (Annex VII. 5)		F3		H4	D3	E2
Class I measuring function, sterile		(F)		H5	D4	(E)
Class IIa		F2		H2	D1	E1
Class IIb	B1	F1		H2	D1	E1
Class III	B1	F1	H1	H2	D1	
Sterilised systems or procedure packs (Art. 12.3)				H3	D2	

Table 2 Possible certificates for NBs under Directive 93/42/EEC;
(F) and (E) = Possible certificates for a NB but not useful

---------- Product certification ---------- ----- Quality system assessment -----

90/385/EEC Active Implantable Medical Devices (AIMDD)						
Type of certificate ⇨	EC Type-Examination Certificate	Certificate of Conformity	EC Design-Examination Certificate	EC Certificate Full Quality Assurance System	EC Certificate Production Quality Assurance	EC Certificate Product Quality Assurance
Module ⇨ Annex ⇨	**Module B** 3	**Module F** 4	**Module H** 2 (4)	**Module H** 2 excluding (4)	**Module D** 5 (3)	**Module E** –
Type of device Other devices than custom-made or intended for clinical investigation	B3	F5	H8	H9	D6	

4. Photos of device

a. In lieu of the actual colored pictures, are brochures acceptable?

b. Do we only submit photo of host device (at all sides)? Photos of accessories are also required? This is the usual deficiency that we received. Can you help us on this please?

REVIEW OF CMDN TECHNICAL REQUIREMENTS

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

On TECHNICAL ISSUES

1. Device Description: Technical Specifications

a. Usually we submit Product Data Sheet, but the evaluator requires more Technical Specification. This is one example: "The submitted Technical Specifications of the product is not sufficient. Technical specification includes the product dimensions, safety standards, technical specs, environmental conditions, etc. It is a set of requirements that you need to achieve or complied for the product to be effective."

b. Received NOD: To submit technical specification of the finished product. Be reminded it may also pertaining to the physical characteristic of the device.

c. One NOD received: asking for Certificate of Analysis. Is this required?

2. Device Description: Raw materials

a. What other document can we submit if the List of Raw Materials is not applicable for the equipment? Can we submit Biocompatibility? List of Critical Components (in IEC 60601-1 Test Report)?

b. Received NOD: To submit all raw materials for all accessories. Is this part of the requirements?

3. Device Description: IFU

a. Evaluator asked for the video on how to use, is this required? How can we upload this to the portal?

4. Declaration of Conformity

a. DOC should be signed by a person responsible. Our DOC is signed by the Head RA but it was not accepted by the evaluator.

b. Do you have a sample of DoC for Class A products that are exempted in the country of origin? What are the standards applied? Will FDA accept in-house or self-declared DoC?

5. Certificate of Conformity

a. Is there a template or sample of a Certificate of Conformity for meterology? Can we also submit IEC 60601-1 Certificate or CAB Certificate?

b. Is the Certificate of Conformity equivalent to Calibration Certificate done by National Metrology Lab? Can we submit Certificate of Traceability?

c. If CoC is required by the evaluator, but the product is not a measuring device, can we submit Declaration letter instead? What other documents to submit as proof?

6. Labels

a. Is the country specific requirement (importer name and distributor address) required to be placed on the main body of the equipment or primary packaging only? Most of the time, there is a challenge to put country specific label in the main device. Some ASEAN countries, only require in the IFU and shipping carton.

b. Location/Position of the labels - do we have specific requirement?

c. For software application: For software CMDN application, what documents do you submit for photos and labeling materials?

d. For software application: How do you implement local labeling requirement (mandatory info) in the IFU of software? Without physical medium, where will we put the local labeling requirements? Can we put it in IFU?

e. Do we need to submit labels of accessories?

f. Approved Country Specific label: When is the implementation date? 6 months grace period from the date of approval? Can we extend the grace period for another 6months?

7. Declaration of Shelf-life

a. What document do you submit for the shelf life of software? Can we submit Declaration that it is not applicable?

On CMDR

1. I submitted multiple CMDN applications. Some were approved while 1 submission was rejected. The reason for rejection is that the evaluator classified sa the product as registrable (for CMDR).

2. We have submitted a CMDN application for class B device which is not included on Annex A. Still, we have received a Denial letter stating that we need to submit the product thru CMDR since this is considered class B registrable medical device.

On VARIATIONS

1. Additional accessories? Variation?

2. Software upgrade - Variation or New Registration; If Software upgrade will only fix bugs, can CDRRHR consider it as Variation? If additional indication, change in specs, new registration or variation? Software update additional features to enhance the product but not changing the intended use - new registration or variation?

3. The manufacturer makes aesthetic changes to the graphical user interface of the medical device software. The changes include providing the user an option to select different color schemes depending on their preference. The company logo was also updated as part of the change.

4. Equipment Version Number Change: No change in product name, indication, Variation or New Registration

OTHERS

1. How do you renew an MDR turned Class A product?
2. BOC:

    a. When we present FDA Circular re extension of full implementation, BOC requires proof of classification of our product. What can we present to them that our product is classified as Class B, C, D?

    b. Pending application: when you mean we can only import/distribute if we have CMDN and pending application, what FDA means by pending application? Is Application Summary and DocTrack sufficient enough to present to BOC?

END OF

Q n A

THANK YOU