FAQ and Common Deficiencies

Requirements	Common Questions and Deficiencies	Answer and Possible Solution
ONLINE FORM	**1. ASEAN Medical Device Directive**	
	a. Clarify the declared classification of the device based on ASEAN Medical Device Directive.	AMDD Ruling
	b. The manufacturer classified the product as Class I. However, the evaluator classified the product as Class B.	AMDD Ruling
	2. Accessories registration as part of the sysmtem	
	a. The accessories included in the machine/configuration depend on the hospita's order/requirements. Do we need to have 1 CMDN per configuration? Or can we put all possible configurations in one CMDN application?	1. Standard/optional: one pathway 2. Per configuration
	b. Accessories that are part of the system, that are registrable, can we include that in the application?	1. Dedicated/Standard (registrable): CMDN as a system; 2. Consummable is universal and registrable: need to apply for registration
	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.	1 CMDN license
	d. For those accessories that are universal to different device, will CDRRHR require a separate standalone CMDN license?	same
	e. Accessories to register with main device - is this only for those classified as medical device?	if included in the shipping
	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.	Of course; different models different registration

	2. Can we have 1 CMDN application, different models? How about for CMDR, can we do it as 1 application?	no
	3. Can we have one CMDN for different model if they differ only in size but same intended use/technical specs?	elaborate
	4. Software	
	a. When applying for machine softwares, do we need to apply separately? Or will the software be part of the machine submission?	if already part of machine 1 app; but if standalone softeare or upgrade need to have separate regi
	b. Do you we need to indicate the software version in our CMDN application?	of course
LEGAL	1. Notarized Declaration	
	a. Will an authenticated CCPIT be accepted in lieu of the notarize declaration letter?	is CCPIT notarized?
	b. For those countries that don't notarize, Is red ribbon/Apostille still acceptable?	what countries?
	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?	Legal
	2. ISO Certificate	
	Is there an alternative document for GMP or ISO 13485 Certificate?	none; ISO 9000 series is still acceptable for other devices
	3. Certificate of Product Registration	
	a. Are CFG AND FSC accepted as proof of registration?	NO
	b. Is EC Certificate still acceptable as proof of registration/CPR? I got a denial the EC Certificate was not accepted by the evaluator.	it depends
	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?	for as long as same manuf and exactly the same product
	d. For those with CMDN license, can we also submit CMDN license as proof of registration when we submit for another CMDN (like diff manuf site)?	No

	4. Photos of device	
	a. In lieu of the actual colored pictures, are brochures acceptable?	Yes; as long as same product
	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?	Yes
TECHNICAL	**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."*	what is the product?; IFU have also tech specs; or upload one pager to inform that additional Tech specs in the IFU.
	b. Received NOD: To submit technical specification of the finished product. Be reminded it may also pertaining to the physical characteristic of the device.	correct
	c. One NOD received: asking for Certificate of Analysis. Is this required?	present CMDN requirements
	2. Device Decription: 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)?	* to discuss with evaluators
	b. Received NOD: To submit all raw materials for all accessories. Is this part of the requirements?	yes
	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?	elaborate
	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.	who is the Head RA? Should be from manuf site or legal manuf

b. Do you have a sample of DoC for Class A products that are exempted in the country of origin? What are the standardsa applied? Will FDA accept in-house or self-declared DoC?	self-declarad by manuf
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?	none; if CAB is accreditated by the country to do metrology testing, yes acceptable
b. Is the Certificate of Conformity equivalent to Calibration Certificate done by National Metrology Lab? Can we submit Certificate of Traceability?	Yes; it is matter of terminology; The measured value for a specific parameter is confirmed to be precised. Example if indicated 37C, the measured value is 37C
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?	elaborate
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.	Yes, should be in the shipping carton and device/equipment. Other option, is to provide CMDN license of the equipment to the hospital posted in the facility (for post market)
b. Location/Position of the labels - do we have specific requirement?	none; as long as visible
c. For software application: For software CMDN application, what documents do you submit for photos and labeling materials?	Ifin the CD: label in the CD
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?	explain how it will be distributed
e. Do we need to submit labels of accessories?	Yes

	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?	Policy issue
	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?	yes
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.	elaborate
OTHERS	1. How do you renew an MDR turned Class A product?	same renewal
	2. BOC:	
	a. When we present FDA Circular re extension of full implementation, BOC requires proof of classificaiton of our product. What can we present to them that our product is classified as Class B, C, D?	not in the FDA Circualr 2020-001A and not in the list of FDA Class A based on FDA Circular 2021-017
	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?	For Class A: Order of Payment
VARIATIONS	1. Additional accessories? Variation?	No; new registration
	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?	Yes; this is another Policy issue

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.	New registration please elaborate; any change in version or model number means there is an upgrade or change in intended use, technical specs so therefore needs new registration.
4. Equipment Version Number Change: No change in product name, indication, Variation or New Registration	