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EXPORTING MEDICAL DEVICES INTO VIETNAM

1. Overview

Medical equipment is specified in Article 2, Decree 98/2021/ND-CP, as follows::

1. "medical device" means any instrument, implant, apparatus, material, in-vitro reagent or calibrator, or software that meets all of the following requirements:
a) The device is intended by the product owner to be used, whether separately or in combination with each other, for human beings for one or more of the following purposes:
- diagnosis, prevention, monitoring, treatment or alleviation of disease, or compensation for an injury or trauma;
- 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 serving diagnosis, monitoring or treatment through examination of specimens derived from the human body.
b) The device does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but that may be assisted in its function by such means to serve the purposes mentioned in Point a of this Clause.
2. "in vitro diagnostic (IVD) medical device" means a reagent, calibrator, control material, instrument, apparatus, equipment or system or other product, whether used alone or in combination, intended by the product owner, to be used in vitro for the examination of specimens derived from the human body.
3. "personalized medical device" means a medical device that is specifically made in accordance with a duly qualified medical practitioner's written prescription, which gives, under his responsibility, specific design characteristics and intended for the sole use of a particular individual."
According to current regulations, all medical devices need to be classified.
Medical devices are classified into 4 categories based on the level of potential risks associated with the technical design and manufacture of such medical devices:

1) Type-A medical devices are those at low level of risks.

2) Type-B medical devices are those at low-moderate level of risks.

3) Type-C medical devices are those at moderate-high level of risks.

4) Type-D medical devices are those at high level of risks.

From July 1, 2022, importers must carry out procedures for announcing standards applicable to class A and B medical devices (From Articles 26 to 28 of Decree 98/2021/ND-CP on site management medical devices and Decree 07/2023/ND-CP amending Decree 98/2021/ND-CP); and procedures for registration of circulation with class C, D medical devices (From Article 29 - Article 32 of Decree 98/2021/ND-CP and Decree 07/2023/ND-CP amending Decree 98/2021 /ND-CP).

2. Documents to be provided

Here are the documents to be provided by the manufacturer, the Vietnamese company (distributor, importer) and some notes:

No.	Required documents	Notes	Risk class A	Type of required documents	Person in charge
1	Application form	Key in via online portal	x	N/A	KENFOX
2	The classification of medical devices	It must be classified by local licensed organization in Vietnam	x	Hard copy	Third party (Consultant selected)

3	The certification to quality management standards for production site (ISO 13485:2016 Certificate)		**x**	Soft copy	Manufacturer
4	The Letter of Authorisation provided by the product owner for the applicant	Must be **legalized by Vietnam** embassy in Mfr's country	**x**	Hard copy	Manufacturer
5	The certificate of eligibility to provide warranty issued by the owner of the medical devices, ***except for single-use medical devices as prescribed by the owner or in case manufacturer does not have warranty policy for the device***	Must be **legalized by Vietnam** embassy in Mfr's country If it is single-use medical device, a letter from manufacturer should be provided	**x**	Soft copy	Manufacturer
6	The technical brief of medical devices.		**x**	Hard copy	KENFOX will prepare, customer will sign and stamp
7	Declaration of Conformity/ Certificate of Product Conformity	by English text color scanned file	**x**	Soft copy	Manufacturer
8	The instructions for use of Medical devices	**by Vietnamese language**	**x**	Soft copy	Customer provide English version, Consultant will translate to Vietnamese version
9	The catalogue	**PDF file** by English text	**x**	Soft copy	Manufacturer
10	The certificate of free sale (FSC) for import medical device	- FSC must list out all of article numbers will be registered in Vietnam and **state the legal manufacturer and all of the manufacturing sites.** - FSC must be **legalized by Vietnam embassy** **-** All information in FSC (including notarization part) must be in English or Vietnamese. If not, a translation into English or Vietnamese must be done.	**x**	Hard copy	Manufacturer
10	The labels to be used when medical devices are circulated in Vietnam. ***(The label for single and carton label for all article codes)***	The label must satisfy requirements specified in this Decree 43/2017/ND-CP. In case, the original label can not comply with the above requirements, we can use the sub labelling showing the required contents by Vietnamese to stick on the product and the original label shall be kept unchanged.	**x**	Soft copy	Manufacturer provides a mock-up of the origin label. KENFOX will prepare the additional label in Vietnamese
11	Relationship letter between the product owner and production site (if this information is not presented on CFS).	This is not a mandatory document and does not assure that MoH can accept or not. It should be better if production site and product owner is mentioned on CFS	**x**	Soft copy	Customer