Regulatory Procedure of Importing and Registering Medical devices , Medical and Laboratory Equipment and In Vitro Diagnostics circulated according to Japanese regulation

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1. Introduction

- Japan is considered one of the reference countries at the Central Administration of Medical Devices in accordance with the decision of the Technical Committee of Medical Devices issued in March 2011.
- Medical Devices in Japan are regulated by the Ministry of Health, Labour and Welfare (MHLW) and its affiliated authority (Pharmaceuticals and Medical Devices Agency " PMDA") .

✓ **MHLW** : is the regulatory authority responsible for establishing and applying safety standards for medical devices and medicines marketed in Japan, issuance of final approval for their registration and their withdrawal from the market.

✓ **PMDA** : is an independent administrative agency working with MHLW to ensure the safety and quality of medical devices and medicines in Japan and is responsible for reviewing the accreditation of medical devices as well as the inspection of QMS/GLP/GCP.

- In order to market medical devices in Japan, it is necessary to appoint a MAH or D-MAH to register products and deal with Japanese regulatory authorities (MHLW/PMDA).

✓ **MAH** is responsible for the medical device and is the holder of the certificates in addition to ensure compliance with quality management system (QMS) requirements, and manage post approval changes and post-market surveillance.

✓ **DMAH** is responsible for registering the medical device in Japan in addition to his responsibility for QMS, Post approval changes and post market surveillance but in this case , the foreign manufacturer is still responsible for the medical device and is the holder of the certificates .

- **Classification of medical devices:**

Classification	Description	Examples	Potential risk
Class I	**MD**: General Medical Devices **IVD**: Analytes defined by MHLW	x-ray film, IVD instruments, Analytes (e.g., CRP, Mg, CSA, HbA1c etc.)	Almost insignificant (extremely low)
Class II	**MD**: Controlled Medical Devices **IVD**: Moderate Risk Class Analytes not Classified as Class I or III	Endoscopes, MRI, CT, ultrasound, tests for analytes (e.g., TACR, TnI, BNP, TSH, etc.)	Have potential risk (moderately low)
Class III & IV	**MD**: Special controlled Medical Devices Risk –**IVD**: New and High Analytes (Class III only)	balloon catheters (III), stents (IV), valves (IV), linear accelerator (III), lithotriptor (III); tests for infectious diseases, cancer markers' Antistreptolysin O, bacterial identification (e.g. HIV, HBs-Ag, CA19-9, HCV-Ab) (III)	Significant (high risk or invasive, potentially life threatening)

- **Certificates issued for medical devices and IVDs according to classification:**

<table>
<tr><th colspan="2">Classification</th><th>Submission category</th><th>Regulatory clearance procedure</th></tr>
<tr><td colspan="2">General medical devices (Class I)</td><td>(Premarket notification)
(TODOKEDE)</td><td>No regulatory approval or marketing authorization is needed . Only a notification to PMDA is needed .</td></tr>
<tr><td rowspan="3">Class II/III</td><td>If conformity assessment with (criteria applicable certification standards)</td><td>(Premarket certification)
(NINSHO)</td><td>RCB (3rd Party) certification is required. Only those class II & III devices for which PMDA has evaluation standards may utilize the RCB certification process. RCB reviews application and then certificate is issued.</td></tr>
<tr><td>Products with no certification standards/ New technology(Novel)</td><td>(Premarket approval)
(SHONIN)</td><td rowspan="2">PMDA review of application and then approval is issued from MHLW.</td></tr>
<tr><td colspan="2">Class IV</td><td>(Premarket approval)
(SHONIN)</td></tr>
</table>

2. Requirements for registration and obtaining import approvals in Egypt :

A) Registration

In addition to the required documents from the applicant contained in the regulatory guideline for registration of local and imported medical devices holding international quality certificates, the following documents have to be uploaded on the MeDevice platform :

SN	Certificate/document	Issuance authority	Content
1	**Free sale certificate legalized**	MHLW	1-MAH &manufacturer/s name and address 2-Trade name, description, codes and sizes 3- Number and date of : marketing approval /Notification / RCB certificate 4-Issuance date
2	**Certificate of conformity in case of Class II and class III medical devices with certification standards**	**registered certification body** (RCB)	
3	**Certificate of QMS conformity (kijun tekigoshou) (Legalized)** (In conformity with ordinance 169) **or** **MDSAP** (Issued to MAH and **foreign manufacturer "if present"**) for all classes and class I devices (if applicable according to JMDN)	PMDA or RCB	1- intended scope should mention manufacturing. 2-Manufacturing facility 3-Issuance date and validity

4	**Declaration Of Conformity according to Japanese regulations** **Signed and stamped**	MAH	1-Trade name, description, codes, sizes and kit/set contents in case of kit/set 2-Quality management system is applied under MAH responsibility 3-Approval route through RCB or PMDA(issuance body and certificate number and date) 4-Regulations/laws/standards applied 5-indication for use 6-classification 7-MAH/D-MAH name and address, legal manufacturer (in case of presence of D-MAH), manufacturing site(s) name(s) and address(s) 8-JMDN
5	**Vigilance commitment** **Signed and stamped** The same procedures for EU classes: I, IIa, IIb and III are followed with Japanese Classes: I,II,III and IV respectively	MAH	As mentioned in guidelines published on EDA website
6	**Technical file** **Signed and stamped**	MAH	

B) Import approvals

Regarding the free sale and quality certificates , the following shall be considered in addition to the documents required to obtain the import approval which are contained in the regulatory guidelines published on EDA's website:

- **In case of medical devices registered according to Japanese regulation: the registration license shall be submitted in addition to renewed certificates {see Annex (a)} only in case of invalidity or expiry of free sale and quality certificates mentioned in the registration license .**
- **In case of medical devices registered according to other regulations other than Japanese one: free sale and quality certificates mentioned in the registration license can be substituted by certificates mentioned in Annex (a)**
- **In case of medical equipment and unregistered medical devices: certificates shall be submitted in accordance with Annex (a)**

Annex (a)

SN	Certificate/document	Issuance authority	Content
1	**Free sale certificate** **legalized**	MHLW	1-MAH &manufacturer/s name and address 2-Trade name, description, codes and sizes 3- Number and date of : marketing approval /Notification / RCB certificate 4-Issuance date
2	**Certificate of conformity in case of Class II and class III medical devices with certification standards**	**registered certification body** (RCB)	———
3	**Certificate of QMS conformity (kijun tekigoshou)** **(Legalized)** (In conformity with ordinance 169) **or** **MDSAP** (Issued to MAH and **foreign manufacturer "if present"**) for all classes and class I devices (if applicable according to JMDN)	PMDA or RCB	1-intended scope **should mention** manufacturing. 2-Manufacturing facility 3-Issuance date and validity
4	**Declaration Of Conformity according to Japanese regulations** **Signed and stamped**	MAH	1-Trade name, description, codes, sizes and kit/set contents in case of kit/set 2-Quality management system is applied under MAH responsibility 3-Approval route through RCB or PMDA(issuance body and certificate number and date) 4-Regulations/laws/standards applied 5-indication for use 6-classification 7-MAH/D-MAH name and address, legal manufacturer (in case of presence of D-MAH), manufacturing site(s) name(s) and address(s) 8-JMDN

N.B.
All documents and labelling data submitted in Japanese must be translated into English either by the Japanese manufacturer or an accredited translation office in Egypt such as (Translation office of Faculty of Al–Alsun)

3. Abbreviations

MHLW	Ministry of Health, Labor and Welfare
PMDA	Pharmaceuticals and medical Devices Agency
MAH	Marketing authorization holder
DMAH	Designated Marketing authorization holder
RCB	Registered certified body
MDSAP	Medical device single audit Program