MEMO 3/2021 HCFLAD

To	:	All Healthcare Facilities in Qatar All Intermediaries and agents of medical devices factories and companies
From	:	Healthcare Facilities Licensing & Accreditation Department
Subject	:	Regulation and control of implantable medical devices
Date	:	13/4/2021

As part of the efforts of Health Care Facilities Licensing and Accreditation Department to ensure the quality and safety of healthcare services, as well as, to regulate and standardize the safe use of Implanted Medical Devices in the state of Qatar; and in according to the ministerial resolution no. (4/2020) announcing the formulation of the Implanted Medical Devices (IMD) Committee; it was decided that:

Import or use of any implantable medical devices is NOT ALLOWED without obtaining the approval of IMD Committee.

Implantable medical devices (IMD) are defined as the devices placed inside a human body during any medical intervention or surgical procedure, whether temporarily or permanently; for example: pacemakers, implantable insulin pumps, hip implants, gastric balloon, coronary stents, intraocular lenses, screws and plates of orthopedics and similar devices.

Follow the attached mechanism to obtain the approval to import or use Implanted medical devices.

For more information please contact:
Implanted Medical Devices Committee: implantedmdcommittee@moph.gov.qa

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Acting Director; Healthcare Facilities Licensing & Accreditation Department
Ministry of Public Health

Implantable Medical Devices Registration Mechanism

Health Facilities Licensing and Accreditation Department

Definition

Implantable medical device (IMD) is defined as the one that placed inside a human body during any medical intervention or surgical procedure, whether temporarily or permanently, for example: pacemakers, implantable insulin pumps, hip implants implantable cardiac defibrillators (ICDs), coronary stents, intraocular lenses, screws and plates of orthopedics, and breast implants ... etc.

Some implantable medical devices may be battery-powered, such as a pacemaker.

There are two pathways for registration, depending on whether the application is for a device model in existing use or a new procurement:

1. For existing medical implants: All healthcare facilities in Qatar using implantable medical devices are required to send a list of all implants currently administered in the facility to the IMD committee for official approval via Implanted Medical Devices Committee: implantedmdcommittee@moph.gov.qa
2. For new medical implants (not in the list of existing IMDs): A manual application must be sent to the IMD committee for approval for procurement, and must be submitted to MoPH Ground Floor office No. 28 or 29, the manual application consisting of the followings:

- Implanted Medical Device Registration Application form to be signed and stamped by the Entity.
- ***Manufacturer's Documents:***

A. Registration certificate of Agents and pharmaceutical companies

B. A copy of valid registration certificate of the factory

C. A valid certificate of Free sale/registration issued by the competent authorities in the country of origin attested by Qatari MoFA

- ***Technical File:***

A. Notarized CE, FDA, or 510(k) certificates along with free sale certificate for the product in the country of the origin (FSC)

B. If the product has only free sale certificate (FSC) in the country of the origin, then another Notarized FSC in one of the following countries must be submitted: (Canada, Australia, Japan, Norway, Switzerland).

C. Post-marketing surveillance Plan.

D. Copy of the Entity Registration Certificate.

E. Copies of product registration certificates in other countries (if Available).

F. Product's information (Finished Product Specifications), including: description, formulation, types, sizes, models, accessories, usages, side effects, warnings, precautions, usage guidelines, photos of the product and the packaging covers, brochures and usage manuals.

G. Provide laboratory requirements and analysis, as well as pricing for certain medical equipment.

H. Acknowledgment of the company that equipment conforms to the specifications as per the Medical Equipment Manual (EC-Declaration of Conformity).

I. Safety data sheet.

Notes:

Entity (the applicant): all Healthcare Facilities in Qatar and all Intermediaries and agents of medical device factories and companies required Form Attached.

Implanted Medical Device Registration Application

APPLICANT DETAILS:

Facility name: .....

License No: .....

Address: .....

Focal point Name: .....

Mobile number: .....

Email: .....

DEVICE DETAILS:

Product name: .....

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Ref. Number: .....

Product Category (specialty):

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Product Classification: .....

MANUFACTURER DETAILS:

Name: .....

Reg. Number: .....

Country: .....

Address: .....

Email: .....

Land line: .....

Website (if exist): .....

P.O Box : .....

Applicant Signature: .....

Stamp Date: .....

Stamp