Entering the Iranian market with Software as a Medical Device

Regulatory pathways, registration and country specific considerations.

Entering the Iranian market with Software as a Medical Device

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NOTE TO READER

This white paper is written in collaboration with MedTech Innovation and should be used as basis for the initial considerations for registration of software as a medical device in Iran. This white paper endeavors giving a better understanding for the device classification, regulatory pathways, and registration requirements. And how a CE marked, or FDA cleared product can be marked in Iran.

Limitations: This white paper reflects a limited view of the approval process in Iran. Readers should only use this white paper as basis for initial considerations before approaching a ministry or consulting firms in Iran.

MedTech Innovation
Ministry of Higher Education and Science – Denmark

1. Regulatory basic in Iran

The recent lifting of Iranian sanctions opens a new market to medical device manufacturers, one of the largest markets in the Middle East. If you are considering a fresh look at the market, here are some things you need to consider before entering the Iranian market with software as a medical device.

Prior to entering the Iranian medical device market, a medical device company should first determine, whether the product is considered a medical device in Iran. Secondly, the device's risk classification will need to be established.

NATIONAL AUTHORITY

The Ministry of Health and Medical Education (MoH [1]) is responsible for the medical device sector and lay down guidelines for registration and classification through a specialized department - the Central Office for Medical Equipment (COME).

For medical devices, the primary regulatory authority is MoH. MoH outlines the regulatory requirements for medical devices in the Medical Cure and Medical Education Act:
http://www.fda.gov.ir/item/2641

You may notice that the text is in Persian, but MoH has an official guidance on the Medical Cure and Medical Education Act in English. The booklet is very sparse, but a great start:
http://imed.fda.gov.ir/Images/Download/17870/Medical_Eq_Reg_final-revised.pdf

MEDICAL DEVICE DEFINITION

The guidance presents a translated definition for medical devices. The definition is very similar to the international definition of a medical device presented by WHO and IMDRF (GHTF/SG1/N071:2012), but it is more elaborate:

Medical Device: Medical supplies, medical devices and supplies, dental and laboratory supplies that are commonly referred to as "medical device" include any product, instrument, equipment, supplies, machinery, implants, materials, laboratory testing and calibration equipment as well as software that manufacturers produce for humans either as a stand-alone items or in connections with other items for one of the following purposes:

- Diagnosis, analysis and observation, prevention, treatment or reduction of illness.
- Support and care for life and its continuation
- Control and prevention of pregnancy
- Disinfection and cleaning of instruments, work areas, medical wastes for optimization of hygienic, treatment and other medical activities.
- Collection of data through laboratory procedures on specimens collected from people for medical aims.
- Diagnosis, analysis and observation, treatment, pacification, remediation or postponement of injury or illness.
- Research, examination, replacement or improvement of physiological or anatomical outcomes.

Like many other countries, the medical device definition is sometimes up for interpretation, and Iran is certainly no different. For that reason, it is highly recommended to contact MoH, if the product is considered a "borderline product" in other countries.

MOH CONTACT INFORMATION

Address: NO. 29, Khark St., After Vali-e-asr Crossroad,
Enghelab Ave., Tehran-Iran
Postal Code: 1415845371
Tel: +98-21-63420
www.imed.ir
info@imed.ir

Link: http://imed.fda.gov.ir/en/page/17843/Contact-Us

Although stand-alone software explicitly can be considered a medical device by the definition in the guidance, this is not necessarily the case. This will be elaborated in Chapter 2.

1. it is hard to get in touch with the ministry through the official contact channel. It is highly recommended that medical device company's partner up with a consulting firm or a local representative.

MEDICAL DEVICE CLASSIFICATION

Medical devices are classified into four classes A, B, C and D, where Class A is the lowest and D is the highest risk class. The classes follow the GLOBAL HARMONIZED TASK FORCE (now: IMDRF) guideline SG1/N015R22.

CLASS	RISK LEVEL	DEVICE EXAMPLES
A	Low Risk	Surgical retractors / tongue depressors
B	Low-moderate Risk	Hypodermic Needles / suction equipment
C	Moderate-high Risk	Lung ventilator / orthopaedic implants
D	High Risk	High Risk Heart valves / implantable defibrillator

The Iranian classification system generally correspond to EU's four classes, as illustrated in the following table:

Iranian Medical Device Classification		European Council Directive 93/42/EEC (MDD)
Class D	Generally Corresponds to	Class III
Class C	Generally Corresponds to	Class IIb
Class B	Generally Corresponds to	Class IIa
Class A	Generally Corresponds to	Class I

REGISTRATION

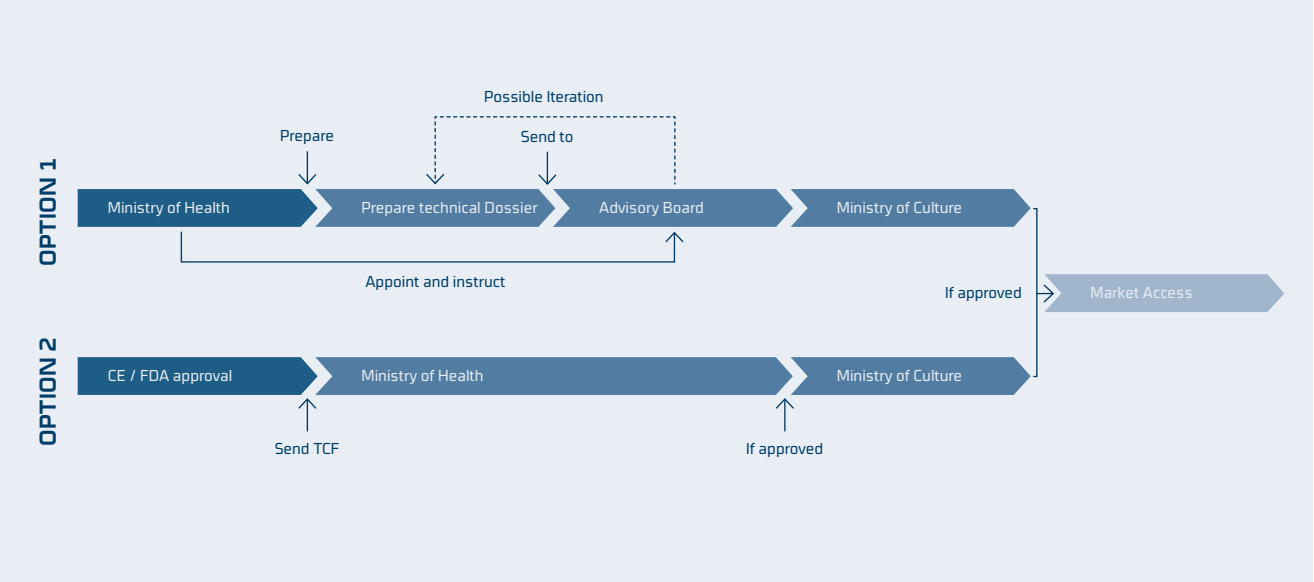
A medical device needs to be registered in Iran, before the device can be placed on the market. Documentation required for registration is like that required for FDA clearance or EU CE marking and follows the STED format for medical device technical documentation.

The link below provides the application form »Application for a Medical Device registration« which also provide a checklist for the technical dossier and need to be send to MoH for approval:
https://www.members.mrepc.com/regulation/Iran%20Forms/IRAN%20Form%20medical%20device%20registration.pdf

2. Software as a medical device

In theory the Iranian government regulates software with a medical purpose. And as mentioned earlier, stand-alone software is mentioned in the definition stated in the guidance. But in practice the MoH is not ready to formally regulate software, but will in time.

In practice the MoH has two approaches for approving software, which depends on whether the product is already approved by another recognized body or not. The two processes are illustrated and described below:



OPTION 1:
THE SOFTWARE IS NOT CE MARKED OR FDA CLEARED

If the product is not approved by a recognized body, the process is a little different from the traditional markets like EU or US. MoH have the following temporary process:

- MoH is contacted (with advantage through a consulting firm or a local representative).
- MoH will ask the manufacturer to prepare a technical dossier (with focus on risk management and clinical evaluation).
- MoH will appoint an advisory board of health professionals, who are able to comment on the clinical value and safety of the software.
- When the medical device company is ready, they send the technical dossier to the advisory board. This process is iterated until the product is approved by the advisory board.
- The manufacturer can then contact Ministry of Culture (MoC) for approval (see Chapter 3).
- The product can be marketed in Iran.

OPTION 2:
PRODUCT IS CE MARKED OR FDA CLEARED

MoH recognizes the CE mark and FDA clearance. If the product is CE marked or FDA cleared, the product does not need to undergo the formal approval process under MoH. But the technical documentation still needs to be reviewed and the product still needs to be registered (regardless of the classification) before market entry. MoH has the following process:

- MoH is contacted and will ask to review the technical documentation for approval (see the previous chapter for formal registration of a medical device).
- MoC is contacted for approval (see Chapter 3)
- The product can be marketed in Iran.

3. Four final considerations before entering the Iranian market

1. LANGUAGE REQUIREMENTS

Most of the population speak Persian/Farsi, which is also the official language of the country. But an English version of the software will be accepted as well, since most of the software in Iran are in English. Especially if the intended user is a professional doctor. From a risk management point of view, it would not be recommended to launch an English version of the software to laypersons.

2. SOFTWARE PROTECTION

It is recommended that your product has a hardware lock for two reasons:

1. Since the product is classified a medical device, a hardware lock (or something similar) is usually used as a risk mitigating factor for preventing non-intended user using the device.

2. Iran does not recognize International software copyright laws to prevent illegal or inexpedient copies or distribution of the software.

3. AUTHORIZED REPRESENTATIVE REQUIREMENTS FOR FOREIGN MANUFACTURERS

Manufacturers with no local sites in Iran shall appoint a local authorized representative. In addition to this requirement, it is strongly recommended that you team up with a local consulting firm or something similar to facilitate the contact with MoH and MoC.

There is no substitute for meeting someone face to face.

4. MINISTRY OF CULTURE (MOC)

MoC is responsible for regulating and restricting access to any media of which the government does not approve. Software applications like Facebook, LinkedIn, and YouTube are for example banned by the MoC. This means that applications and websites shall be registered and approved by MoC, before the software can be marketed. This restriction should be investigated before launch - especially if the software is using external software to support training material - for example YouTube videos.

In the worst-case scenario, the MoC can block the software, or as a minimum delay time-to-market.

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