

MDS-IR4

Implementing Rule on
Establishment Licensing

Version Number: 5.0
Version Date: 26/7/2018



Chapter One

General Rules

Article One

This document is an Implementing Rule adopted by the Saudi Food and Drug Authority (SFDA) on the basis of the Medical Devices Interim Regulation and, in particular, Article Forty Five thereof, issued by Saudi Food and Drug Authority Board of Directors Decree number 1-8-1429 and Dated 27 December 2008.

Article Two

This Implementing Rule, in accordance with the Medical Devices Interim Regulation, specifies and refines the provisions of its Chapter Five in relation to the licensing of establishments involved in the importation and/ or distribution of medical devices to the KSA market.

Article Three: Definitions

The following definitions apply:

KSA: means the Kingdom of Saudi Arabia.

SFDA: means the Saudi Food and Drug Authority.

Party: means any natural or legal person.

Medical Device: means any instrument, apparatus, implement, machine, appliance, implant, in vitro reagent or calibrator, software, material or other similar or related article:

- A. Intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the specific purpose(s) of:
 - Diagnosis, prevention, monitoring, treatment or alleviation of disease;
 - Diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap;
 - 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 for medical or diagnostic purposes by means of in vitro examination of specimens derived from the human body.

and

- B. Which does not achieve its primary intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its intended function by such means.

Applicant: means any party established within the KSA required to provide information for establishment licensing purposes.

Authorized Representative (AR): means any natural or legal person established within the KSA who has received a written mandate from the manufacturer to act on his behalf for specified tasks including the obligation to represent the manufacturer in its dealings with the SFDA.

Distributor: means any natural or legal person in the supply chain who, on his own behalf, furthers the availability of a medical device to the end user.

Importer: means any natural or legal person in the supply chain who is the first to make a medical device, manufactured in another jurisdiction, available in the KSA.

Manufacturer: means any natural or legal person with responsibility for design and manufacture of a medical device with the intention of making it available for use, under his name; whether or not such a medical device is designed and/or manufactured by that person himself or on his behalf by another person.

Placing on the market: means the first making available in return for payment or free of charge of a medical device, with a view to distribution and/ or use within the KSA, regardless of whether it is new or fully refurbished.

Local Manufacturer: means manufacturer established within the KSA.

National Registry Number: means the number issued to a person by the SFDA under the establishment registration provisions of the Medical Devices Interim Regulation.

Person: means a term that includes legal entities such as a corporation, partnership or an association.

Supply Chain: means different elements of the distribution activities of a medical device occurring between it being available for importation into the KSA and it being put into service.

Establishment: means any place of business within the KSA that is involved in the manufacture and/or placing on the market and/or distribution of medical devices or acting on behalf of the manufacturer.

Labelling: means written printed or graphic matter,

- A. Affixed to a medical device or any of its containers or wrappers;
- B. Information accompanying a medical device related to its identification and/or technical description;
- C. Information accompanying a medical device related to its use, but excluding shipping documents.

Registration: means the process by which a party submits information to the SFDA regarding the identification and establishment location(s) of the manufacturer and other parties, responsible for supplying a medical device(s) to the KSA market.

Licensing: the process whereby the SFDA issues an establishment license to a party which permits it to undertake the activity of either importing or distributing a medical device within the KSA or acting on behalf of the manufacturer.

Healthcare provider: any party, governmental or private, provides healthcare services with KSA including health clinics.

Quality management system (QMS): A quality management system (QMS) is a formalized system that documents processes, procedures, and responsibilities for achieving quality policies and objectives.

Article Four: General principles

A. Chapter Five of the Medical Devices Interim Regulation requires:

1. Importers and their branches and warehouses shall have an establishment license issued by the SFDA. Such organizations shall submit the information specified in Article Seven of this Implementing Rule and have post-licensing responsibilities specified in Article Nine.
2. Distributors and their branches and warehouses shall have an establishment license issued by the SFDA. Such organizations shall submit the information specified in Article Twelve of this Implementing Rule and have post-licensing responsibilities specified in Article Fourteen.
3. Local manufacturers and their manufacturing sites shall have an establishment license issued by the SFDA. SFDA shall publish, on its website, a guidance document to specify the requirements for local manufacturers licensing.

- B. This Implementing Rule specifies and/or completes the relevant requirements of the Medical Devices Interim Regulation in order to ensure their uniform application by all the parties involved.



Chapter Two

Licensing of Establishments Importing Medical Devices

Article Five: General

- A. Establishment licensing is intended to ensure that any organization importing medical devices into the KSA is able and committed to undertake:
 - 1. All necessary customs procedures;
 - 2. The procedures specified by the manufacturer for storage, transportation, and handling of the medical devices it imports.
 - 3. The appropriate procedure to trace medical devices through that part of the supply chain with which it is directly involved.
- B. Only organizations holding a valid establishment license, issued by the SFDA, are permitted to import medical devices into the KSA.

Article Six: Parties subject to establishment licensing for importation activities

- A. Importers or any natural or legal person performing importation activities, hereafter referred to as applicants, are required to obtain an establishment license for this activity from the SFDA. Each of these organizations must be in possession of an Establishment National Registry Number, assigned to it by the SFDA, before it applies for an establishment license.
- B. Healthcare providers and the professionals working with them, importing devices for their own use only, are not required to be licensed.

Article Seven: Information to be submitted for the licensing of establishments involved in the importation of medical devices

For the purposes of establishment licensing, the applicant shall complete the electronic application available on the MDEL and thereby submit information to the SFDA. Where the applicant intends to import medical devices from more than one manufacturer, the applicant shall provide such information for all the manufacturers, as follows:

- A. The name of the overseas manufacturer of the medical devices that the applicant imports or intends to import, together with the name of that manufacturer's licensed authorized representative and its establishment National Registry Number.
- B. An attestation that the manufacturer has been informed, through its authorized representative, of the applicant's intention to import its medical devices into the KSA.
- C. An attestation that the importer has used its best endeavors to establish that the imported device(s) is in compliance with the relevant provisions of the Medical Devices Interim Regulation and its Implementing Rules.
- D. The medical device category and generic device group the applicant intends to import from the manufacturer.
- E. A documented procedure the applicant will follow to trace individual medical devices through that part of the supply chain with which it is directly involved, and an attestation that it will implement and maintain this procedure.

- F. A documented procedure the applicant will follow to comply with the manufacturer's requirements for the storage, handling, and transport of medical devices it imports, and an attestation that it will implement and maintain this procedure.
- G. Evidence that the quality management system (QMS) is in place and in compliance with SFDA QMS requirements. SFDA shall publish, on its website, a guidance document to specify these requirements.
- H. A commitment to inform the SFDA of any change to the information previously submitted, within 10 calendar days of the change occurring.
- I. The date when the information is submitted.

Article Eight: Responsibilities of the SFDA

The SFDA shall:

- A. Acknowledge to the applicant that the information required for establishment licensing has been received and is sufficient;
- B. Verify that the information submitted by the applicant is satisfactory and meets the requirements of the Medical Devices Interim Regulation and of this Implementing Rule;
- C. Issue the applicant with an establishment license for its importation activities, valid for one year, when it is satisfied that the relevant requirements have been met; and
- D. On an annual basis, request each licensed importer to confirm that the information previously provided continues to be accurate.

Article Nine: Post-license responsibilities of organizations importing medical devices into the KSA.

Licensed organizations involved in the importation of medical devices are required to comply with the relevant requirements of the Medical Devices Interim Regulation and its Implementing Rules. These include:

- A. To act in accordance with the procedures or practices referred to in Article Seven, paragraphs C, D, F, G, H and I of this Implementing Rule.
- B. To ensure that each medical device presented to the KSA customs authorities is accompanied by all the necessary documentation and, in particular, by the:
 - 1. Documentation required by the KSA customs authority.
 - 2. Name and contact details of the organization responsible for importing the device.
 - 3. Names and contact details of the manufacturer of the medical devices and, when applicable, of his authorized representative.
 - 4. Identification of the medical devices.
 - 5. Marketing authorization issued by the SFDA that permits the medical devices to be placed on the KSA market; and
 - 6. Declaration of Conformity that the imported device complies with the requirements of the Medical Devices Interim Regulation and the relevant Implementing Rules, signed by the manufacturer.
- C. To import only those medical devices that comply with the requirements of the Medical Devices Interim Regulation and the relevant Implementing Rules.
- D. Where the importing organization subsequently receives information that leads it to believe that a medical device with which it has been involved was not in conformity with the relevant requirements of the Medical Devices Interim Regulation and/or its Implementing Rules, it shall

take the appropriate measures as specified in the Implementing Rule MDS-IR 7 on post-marketing surveillance.



Chapter Three

Licensing of Establishments involved in the Distribution of Medical Devices within the KSA

Article Ten: General principles

- A. Establishment licensing is intended to ensure that any organization distributing medical devices within the KSA is able to undertake the procedures specified by the manufacturer for storage, transportation, handling and tracing the medical devices it distributes.
- B. Only organizations holding a valid establishment license, issued by the SFDA, are permitted to distribute medical devices within the KSA.

Article Eleven: Parties subject to establishment licensing for distribution activities

Distributors and any natural or legal person performing distribution activities, hereafter referred to as applicants, are required to obtain an establishment license for this activity from the SFDA. Where a retail pharmacy distributes medical devices, it shall be subject to licensing requirements for these activities alone. Each of these organizations must be in possession of an establishment National Registry Number, assigned to it by the SFDA, before it applies for an establishment license.

Article Twelve: Information to be submitted for the licensing of establishments involved in medical device distribution

For the purposes of establishment licensing, the applicant shall complete the electronic application available on the MDEL and thereby submit information to the SFDA. Where the applicant intends to distribute medical devices from more than one manufacturer, the applicant shall provide such information for all the manufacturers, as follows:

- A. The name of the manufacturer of the medical devices that the applicant intends to distribute, together with the Establishment National Registry Number of either the local manufacturer or, for medical devices manufactured outside the KSA, the authorized representative.
- B. An attestation that either the local manufacturer or the authorized representative together with the importer, as applicable, has been informed of the applicant's intention to distribute its medical device(s) within the KSA.
- C. The medical device category or generic device group the applicant intends to distribute within the KSA.
- D. A documented procedure the applicant will follow to trace individual medical devices through that part of the supply chain with which it is directly involved; and an attestation that it will implement and maintain this procedure.
- E. A documented procedure the applicant will follow to comply with the manufacturer's requirements for the storage, handling, and transport of medical devices it distributes; and an attestation that it will implement and maintain this procedure.
- F. A commitment to be involved in the manufacturer's post-market surveillance activities described in Implementing Rule MDS-IR 7.
- G. A commitment to inform the SFDA of any change to the information previously submitted within 10 calendar days of the change occurring.

- H. Evidence that the quality management system (QMS) is in place in compliance with SFDA QMS requirements. SFDA shall publish, on its website, a guidance document to specify these requirements.
- I. A commitment to use its best endeavors to establish that the devices it distributes are in compliance with the relevant provisions of the Medical Devices Interim Regulation and its Implementing Rules.
- J. The date when the information is submitted.

Article Thirteen: Responsibilities of the SFDA

The SFDA shall:

- A. Acknowledge to the applicant that the information required for establishment licensing has been received and is sufficient;
- B. Verify the information submitted by the applicant is satisfactory and meets the requirements of the Medical Devices Interim Regulation and of this Implementing Rule;
- C. Issue the applicant with an establishment license for its distribution activities, valid for one year, when it is satisfied that the relevant requirements have been met; and
- D. On an annual basis, request each licensed distributor to confirm that the information previously provided continues to be accurate.

Article Fourteen: Post-license responsibilities of distributors

Licensed organizations involved in the distribution of medical devices within the KSA are required to comply with the relevant requirements of the Medical Devices Interim Regulation. These include:

- A. To act in accordance with the procedures or practices referred to in Article Twelve, paragraphs C, E, F, G, H and I of this Implementing Rule.
- B. To ensure its staff and other resources are sufficient in number, skills and qualifications to discharge the obligations placed upon it by each distribution agreement.
- C. For the medical devices it distributes, to ensure each medical device is accompanied by its labeling and other relevant documentation.
- D. To use its best endeavors to ensure it distributes only those medical devices that comply with the requirements of the Medical Devices Interim Regulation and the relevant Implementing Rules.
- E. Where the distribution organization subsequently receives information that leads it to believe that a medical device with which it has been involved was not in conformity with the requirements of the Medical Devices Interim Regulation and/or an Implementing Rule he shall take the measures as specified in the Implementing Rule MDS-IR 7 on Post-marketing Surveillance.

Chapter Four

Refusal or Suspension of an Establishment License

Article Fifteen: Refusal to license

- A. The SFDA shall refuse to issue a license for establishments involved in importation and/or distribution of medical devices, if it has reasonable grounds to believe that issuing such a license would not ensure an appropriate level of quality and/or performance of the devices when they are put into service by the end user.
- B. If the SFDA intends to refuse the establishment license, it shall notify the applicant in writing of the reasons of the refusal and information of the procedure to appeal the action taken.

Article Sixteen: Suspension or withdrawal of an issued license

- A. The SFDA shall suspend the license of establishments involved in importation and/or distribution of medical devices, if it has reasonable grounds to believe that the licensee has contravened any of the relevant provisions of the Medical Devices Interim Regulation, and/or of this Implementing Rule, or has made a false or misleading statement in its application.
- B. Before suspending an establishment license, the SFDA shall send the licensee a notice that sets out the reason for the intended suspension and, if appropriate, corrective actions to be taken as well as the time during which they shall be implemented.
- C. The suspended establishment license shall be reinstated if the situation that gave rise to its suspension has been properly corrected.
- D. If the required corrective actions have not been adopted in due time, the establishment license shall be withdrawn.
- E. The SFDA shall provide information to the licensee on the procedure to appeal the action taken.

Chapter Five General Provisions

Article Seventeen: Application date

- A. This Implementing Rule and the corresponding application forms referred to in Articles Seven and Twelve shall be published and made available on the SFDA Website.
- B. The application date of this Implementing Rule and of the provisions of the Medical Devices Interim Regulation to which it relates is February 14th 2011.
- C. Applications for an establishment license may be submitted to the SFDA from the application date referred to in paragraph B of this Article.



Annex (1): List of Changes on the Previous Version

| Article No. | Change Type | From | To |
|------------------|-------------|--|---|
| Article One | Edit | in particular, Article 43 thereof, | in particular, Article Forty Five thereof, |
| Article Three | Add | - | Healthcare provider: any party, governmental or private, provides healthcare services within KSA including health clinics. |
| Article Three | Delete | Applicant: means any party established within the KSA required to provide information for establishment licensing purposes. | - |
| Article Three | Add | - | Quality management system (QMS): A quality management system (QMS) is a formalized system that documents processes, procedures, and responsibilities for achieving quality policies and objectives. |
| Article Four/A/1 | Edit | Organizations involved in the importation of medical devices into the KSA shall have an establishment license for this activity, issued by the SFDA. | Importers and their branches and warehouses shall have an establishment license issued by the SFDA. |
| Article Four/A/2 | Edit | Organizations involved in the distribution of medical devices within the KSA shall have an establishment license for this activity, issued by the SFDA | Distributors and their branches and warehouses shall have an establishment license issued by the SFDA |
| Article Four/A | Add | - | 3. Local manufacturers and their manufacturing sites shall have an establishment license issued by the SFDA. SFDA shall publish, on its website, a guidance document to specify the requirements for local manufacturers licensing. |
| Article Six/B | Edit | Healthcare facilities and the professionals working within them | Healthcare providers and the professionals working with them |
| Article Seven/E | Edit | A general description of the procedure the applicant | A documented procedure the applicant |

| | | | |
|--------------------|--------|--|---|
| Article Seven/F | Edit | A general description of the procedure the applicant | A documented procedure the applicant |
| Article Seven | Add | - | G. Evidence that the quality management system (QMS) is in place and in compliance with SFDA QMS requirements. SFDA shall publish, on its website, a guidance document to specify these requirements. |
| Article Nine/A | Edit | paragraphs C, D, F, G and H of this Implementing Rule | paragraphs C, D, F, G, H and I of this Implementing Rule |
| Article Nine/C | Edit | with the requirements of the Medical Devices Interim Regulation , as signified by the SFDA issuing the manufacturer with a written marketing authorization. | with the requirements of the Medical Devices Interim Regulation and the relevant Implementing Rules |
| Article Twelve/D | Edit | A general description of the procedure the applicant | A documented procedure the applicant |
| Article Twelve/E | Edit | A general description of the procedure the applicant | A documented procedure the applicant |
| Article Twelve | Add | - | H. Evidence that the quality management system (QMS) is in place in compliance with SFDA QMS requirements. SFDA shall publish, on its website, a guidance document to specify these requirements. |
| Article Fourteen/A | Edit | paragraphs C, E, F, G and H of this Implementing Rule | paragraphs C, E, F, G, H and I of this Implementing Rule |
| Article Fourteen/B | Edit | sufficient in number, and skills | sufficient in number, skills and qualifications |
| Article Fourteen/D | Delete | , as signified by the SFDA issuing the manufacturer with a written marketing authorization. | - |
| Article Fourteen | Delete | F. For implantable medical device, distributor shall provide the name of the healthcare provider who received the device, the date of the delivery, and any other relevant information to the SFDA relevant electronic system. | - |

