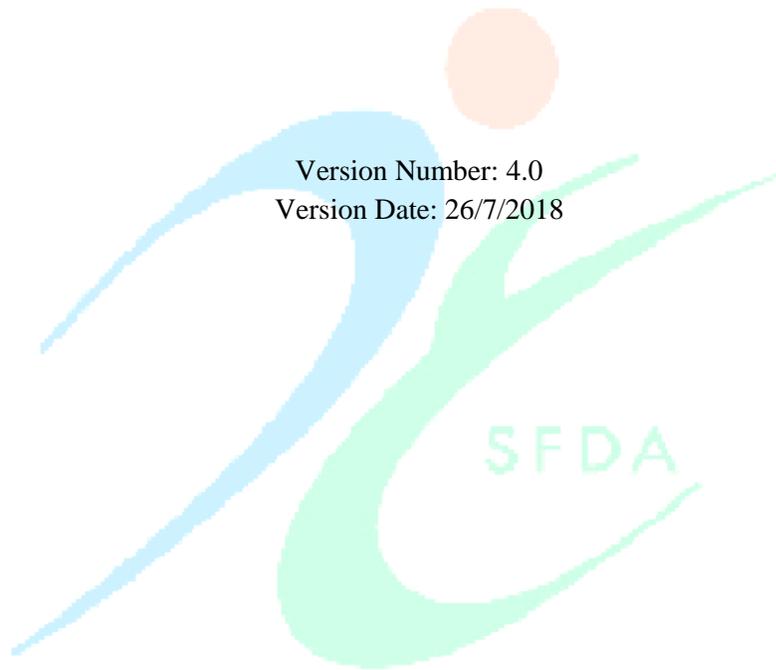


MDS-IR5

Implementing Rule on
Licensing of Authorized Representatives

Version Number: 4.0
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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 (SFDA) 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 Six in relation to the licensing of authorized representatives mandated by a manufacturer to act on his behalf within the KSA.

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.

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: manufacturer established within the KSA.

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

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

Supply chain: 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: 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.

Generic device group: means a set of devices having the same or similar intended uses or commonality of technology allowing them to be classified in a generic manner not reflecting specific characteristics.

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: 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.

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

Global Harmonization Task Force (GHTF): countries working to achieve harmonization in medical device regulation among themselves. These countries are Australia, Canada, Japan, the USA and the EU/EFTA.

Note: GHTF was disbanded in 2012 and its mission has been taken over by the IMDRF.

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 Six of the Medical Devices Interim Regulation requires organizations authorized by a manufacturer to act on his behalf in the KSA to have an establishment license for this activity, issued by the SFDA. Such organizations shall be authorized to perform the activities specified in Article Six of this Implementing Rule and have responsibilities specified in Article Seven.
- B. A particular organization or person involved in the importation of medical devices and/or their distribution as well as acting as an authorized representative for one or more manufacturers shall comply with the requirements of both this Implementing Rule and with Implementing Rule MDS – IR4 on establishment licensing.
- C. This Implementing Rule specifies and refines 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 an Authorized Representative

Article Five: General

- A. Establishment licensing is intended to ensure that an authorized representative
 - 1. Has been properly appointed to represent a particular manufacturer in the KSA;
 - 2. Possesses a written mandate describing the activities for which it acts on the manufacturer's behalf and these are sufficient to ensure the proper application of the relevant provisions of the Medical Devices Interim Regulation; and
 - 3. Has set up appropriate procedures to comply with the mandated activities.
- B. Only an authorized representative holding a valid establishment license, issued by the SFDA, is permitted to legally act on behalf of the manufacturer in relation to the relevant provisions of the Medical Device Interim Regulation and the corresponding Implementing Rules. Each authorized representative shall be in possession of an Establishment Registry Number before it applies for a license.
- C. The authorized representative shall have separate licenses for each manufacturer it represents within the KSA.
- D. Where a manufacturer intends to make available more than one category or generic device group of medical device to the KSA market, it may designate a different authorized representative for each device category or generic device group.
- E. The authorized representative shall apply a quality management system (QMS). SFDA shall publish, on its website, a guidance document to specify the requirements of QMS, and shall ensure the compliance to these requirements.

Article Six: Activities to be performed by an authorized representative

- A. The mandate established between the manufacturer and the authorized representative shall be in writing, specify the mandated activities and be subject to the laws of the KSA.
- B. The mandate shall, at a minimum, allow the authorized representative to:
 - 1. Represent the manufacturer in its dealings with the SFDA.
 - 2. List each medical device category or generic device group intended to be supplied to the KSA market.
 - 3. Access the electronic application form available on the medical devices marketing authorization MDMA portion of the SFDA website and provide the SFDA with all necessary supporting documentary evidence, required by CHAPTER II of Implementing Rule MDS – IR 6 Marketing Authorization.
 - 4. Cooperate with the SFDA on evaluations and actions taken during market surveillance and/or vigilance procedures described in Implementing Rule MDS-IR7 Post-marketing Surveillance.
 - 5. Make the following information available to the SFDA when so required in relation to its marketing surveillance activities:
 - The marketing authorization issued by the SFDA for the listed medical devices.
 - The documentation which was used to demonstrate compliance with the Regulation of the relevant GHTF founding member jurisdictions.

- The documents approved by the SFDA demonstrating compliance with the specific Saudi provisions referred to in Article 6 of Implementing Rule MDS – IR 6 Marketing Authorization.
- 6. Inform the SFDA of any adverse events that have occurred outside the KSA but have consequences for medical devices that have been authorized to be placed on the market of the KSA. The authorized representative shall explain the circumstances and provide information on the corrective action the manufacturer has taken or intends to take.
- 7. Inform the SFDA of all field safety corrective actions resulting from post-marketing follow-up investigations performed by the manufacturer for medical devices that have been authorized to be placed on the market of the KSA. The authorized representative shall explain the reason for the corrective action and provide information on the action the manufacturer has taken or intends to take.
- 8. Cooperate with parties involved in distribution and importation activities, installation and maintenance of medical devices that have been placed on the KSA market under its mandate.
- C. The manufacturer may, under his sole responsibility, authorize his representative to perform tasks other than those specified in paragraph B of this Article.

Article Seven: Obligations of the authorized representative

- A. The authorized representative shall be established in the KSA.
- B. The authorized representative shall complete the electronic licensing application form MDEL available on the SFDA website and inform the SFDA without delay of any changes made to the information submitted.
- C. The authorized representative shall establish, document and implement the procedures necessary for it to perform its mandated tasks and attach the relevant documentation when completing the MDEL.

Article Eight: Responsibilities of the SFDA

The SFDA shall for each manufacturer the authorized representative represents:

- 1. Acknowledge to the authorized representative that the application form and its attachments has been received;
- 2. Verify the information submitted by the applicant is satisfactory and meets the requirements of the Medical Devices Interim Regulation, of Articles Six and Seven of this Implementing Rule, and of the mandate;
- 3. Verify that the authorized representative's implementation procedures appear appropriate to the performance of its mandated tasks;
- 4. Issue the authorized representative with a license, valid for one year, when it is satisfied that the relevant requirements have been met;
- 5. On an annual basis, request each licensee to confirm that the information previously provided continues to be accurate;
and
- 6. Evaluate any changes to the mandate and take appropriate actions if required.

Chapter Three

Refusal or Suspension of a License

Article Nine: Refusal to license

- A. The SFDA shall refuse to issue a license for an authorized representative if the mandated tasks and/or the proposed procedures are insufficient to ensure the proper implementation of the Medical Device Interim Regulation and this Implementation Rule.
- B. If the SFDA intends to refuse the 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 Ten: Suspension or withdrawal of an issued license

- A. The SFDA shall suspend the license of an authorized representative if it has reasonable grounds to believe that the licensee has contravened any of the relevant provisions of the Medical Devices Interim Regulation, or of this Implementing Rule, or has made a false or misleading statement in its application.
- B. The SFDA shall suspend the license of an authorized representative if it is of the view that he has not correctly fulfilled the mandates tasks.
- C. Before suspending a 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.
- D. The suspended license shall be reinstated if the situation that gave rise to its suspension has been properly corrected.
- E. If the required corrective actions have not been adopted in due time, the license shall be withdrawn.
- F. The SFDA shall provide information to the licensee on the procedure to appeal the action taken.

Chapter Four General Provisions

Article Eleven: Application date

- A. This Implementing Rule shall be published and made available on the SFDA website.
- B. The application date of this Implementing Rule and the provisions of the Medical Devices Interim Regulation to which it relates is February 14th 2011.
- C. Applications for the licensing of an authorized representative 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	-	<p>Global Harmonization Task Force (GHTF): countries working to achieve harmonization in medical device regulation among themselves. These countries are Australia, Canada, Japan, the USA and the EU/EFTA.</p> <p>Note: GHTF was disbanded in 2012 and its mission has been taken over by the IMDRF.</p>
Article Three	Add	-	<p>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.</p>
Article Five	Add	-	<p>E. The authorized representative shall apply a quality management system (QMS). SFDA shall publish, on its website, a guidance document to specify the requirements of QMS, and shall ensure the compliance to these requirements.</p>
Article Six/B/8	Edit	involved in distribution activities	involved in distribution and importation activities
Article Eight	Edit	A. The SFDA shall for each manufacturer	The SFDA shall for each manufacturer