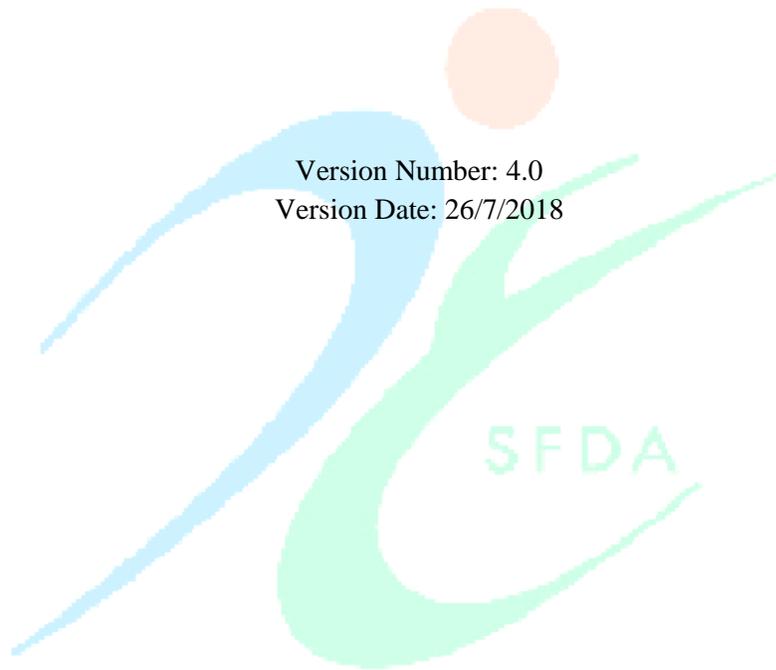


MDS-IR6

Implementing Rule on
Marketing Authorization

Version Number: 4.0
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 Chapters Two and Six in relation to the validation of documentation to be provided to, or kept available for inspection by, the SFDA in order to obtain a medical device marketing authorization.

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.

Marketing Authorization Number: means the code assigned by the SFDA to one or more medical devices, that have been included in a single marketing authorization application, to indicate these devices are authorized to be placed on the KSA market.

Medical Device National Listing Number: means the code assigned by the SFDA to a single medical device, that has been included in a marketing authorization application, to indicate the device is authorized to be placed on the KSA market and facilitate traceability.

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

Lay person: individual that does not have formal training in a relevant field or discipline.

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.

Supply(ing) to the market: the making available, in return for payment or free of charge, of a device, other than a device intended for clinical or performance evaluation, with a view to distribution and/or use on the market.

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.

Labeling: 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.

Fully refurbished medical device: means a used device that has been returned to a state which would allow it to be subject to the same conformity assessment procedures as applied to the original device.

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.

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.

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. Chapters Two and Six of the Medical Devices Interim Regulation require manufacturers wishing to supply a medical device in the KSA, to provide the required documents that show the medical device complies with the medical device regulations of at least one of the GHTF Founding Member jurisdictions, and additionally with provisions specific to the KSA concerning labeling and conditions of supply and/or use. This Implementing Rule specifies and/or completes the provisions of the Medical Devices Interim Regulation in relation to marketing authorization process.
- B. According to Article Six of the Medical Devices Interim Regulation, the SFDA may issue marketing authorization in accordance with provisions specified by the SFDA. SFDA shall publish, on its website, a guidance document to specify these provisions.



Chapter Two

Documentation to be Provided to, or Kept Available for Inspection by the SFDA

Article Five: General requirement

- A. The manufacturer shall either directly, or where the manufacturer is established overseas, through his authorized representative, access the electronic application form available on the Medical Devices Marketing Authorization (MDMA) portion of the SFDA website and provide the SFDA with documentary evidence, as specified in Articles Six, Seven and Eight.
- B. The SFDA shall adopt and publish a guideline to ensure a coherent and uniform application of Articles Six to Nine.
- C. Manufacturers 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: General information

- A. Contact details for the manufacturer.
- B. Where the manufacturer is established within the KSA, his establishment National Registry Number.
- C. Where the applicant is an authorized representative of a manufacturer established outside the KSA, his contact details, establishment National Registry Number and the License Number assigned to him by the SFDA.
- D. The name and contact details of the person responsible for completing the MDMA.
- E. Information on the medical device the manufacturer wishes to supply to the market.
- F. An indication of whether or not the device that is the subject of the application complies with the relevant medical device regulations of one or more of the GHTF Founding Member jurisdictions (namely Australia, Canada, Japan, USA or the EU).
- G. Documentary evidence that the medical device complies with the regulations of the particular jurisdiction that has been selected as a basis of the application as described in Article Seven.
- H. Documentary evidence that the medical device complies with the National Provisions of the KSA as described on SFDA website.
- I. An undertaking by the manufacturer to inform the SFDA of all measures and actions taken , either within or outside the KSA, which may affect the medical devices supplied to the KSA, as specified in Implementing Rule MDS-IR 7 on Post- marketing Surveillance.
- J. Manufacturers of contact lenses and laser surgical equipment that are intended to be used only for cosmetic rather than medical purposes are subject to this Implementing Rule.

Article Seven: Information and documentary evidence

The applicant shall provide the SFDA with information and documentary evidence, as follows:

- A. The classification of the medical device, or in-vitro medical device, according to the regulations that apply.
- B. Evidence that the medical device complies with the conformity assessment requirements that apply to it in the jurisdiction, including any registration or listing requirements.
- C. Evidence, where such is required, that the manufacturer's quality management system is in place, covers the appropriate processes and is subject to independent audit. Where the manufacturer has

decided voluntarily to implement a quality system, evidence shall be provided of its proper application.

- D. Where the manufacturer's claim that its device complies with the medical device regulations is not subject to premarket review by the Regulatory Authority (RA), or a Conformity Assessment Body appointed by the RA to act on its behalf, an indication of the location of the technical information that supports the manufacturer's claim. The SFDA may, when duly justified, require the manufacturer to provide a summary of these documents.
- E. An attestation that the medical device complies with the provisions of the medical device regulations that apply within the GHTF Founding Member jurisdiction that has been selected as the basis of the application.
- F. A copy, in electronic form, of the advertising and marketing materials that will be used in the KSA, if any.

Article Eight: Language requirements for the documentation to be provided to, or kept available for inspection by, the SFDA

- A. Documents to be provided to the SFDA shall be in English, unless the SFDA has given prior agreement that another language is acceptable. However, where the language used is other than English, a summary and/or translation of the relevant parts of the document shall be provided in English.
- B. The manufacturer shall indicate to the SFDA the location of the technical documents that support its application. When duly justified, the SFDA may request the applicant to provide parts of this technical documentation. Where the language used in such documentation is other than English, the applicant shall indicate this fact to the SFDA and may be requested to provide an English translation of the relevant parts of such documents.
- C. Labeling in the English language is acceptable where the user(s) of the medical device is likely to be professionally qualified. If the device is for use by a lay person, labeling shall be in both the Arabic and English languages.
- D. The following documents shall be in English:
 - 1. Measures related to the application of the specific Saudi requirements;
 - 2. The declarations attesting that the medical devices comply with the Medical Devices Interim Regulation.
 - 3. The undertaking to transmit to the SFDA all reportable adverse events;
 - 4. The mandate nominating the authorized representative, if any.
 - 5. Instructions on training of users or other persons.
- E. Instructions for the handling, storage, transportation, installation, maintenance and, disposal of the medical devices shall be in English and, where justified, in Arabic.
- F. Advertising and marketing information shall be in English and, where the user is a lay person, in Arabic and English.

Chapter Three

Authorization Procedure

Article Nine: The evaluation of the application and validation of documents

- A. The evaluation process will verify if all the appropriate information is provided.
- B. When the required information and documentation has been provided to the MDMA, the SFDA may allocate applications with their associated documents to a CAB (Conformity Assessment Body), duly appointed to assist the SFDA, and ask it to verify that the medical device complies with the provisions specified in the Medical Devices Interim Regulation.
- C. The SFDA and/or CAB determine the adequacy of the documentary evidence in support of the applicant's attestation of conformity with the Medical Devices Interim Regulation.
- D. Where the evidence offered is inadequate, the SFDA will request the applicant to provide additional technical documentation but, where it does so, must justify such a request. The SFDA may also verify directly with the organizations that have issued any certificates provided by the applicant that they have not expired and/or the conditions of their validity.
- E. The CAB may request the SFDA to interrogate the NCMDBR database for any reported incidents that involve the medical device that is the subject of the market authorization application.
- F. When the CAB has reached a conclusion as to whether or not the manufacturer has met the requirements of the Medical Devices Interim Regulation it shall recommend to the SFDA that it may issue the marketing authorization.

Article Ten: Marketing authorization

Once satisfied with the information received, the SFDA issues:

1. A written marketing authorization, in both Arabic and English, to the manufacturer that permits the relevant medical devices to be placed on the market of the KSA. It shall indicate the dates of both its issue and expiry, having taken account, among other factors, of the conditions of validity of the authorization in the GHMF Founding Member jurisdiction, if any.
2. A Marketing Authorization Number.
3. Medical Device National Listing Numbers for the medical devices included in the marketing authorization.

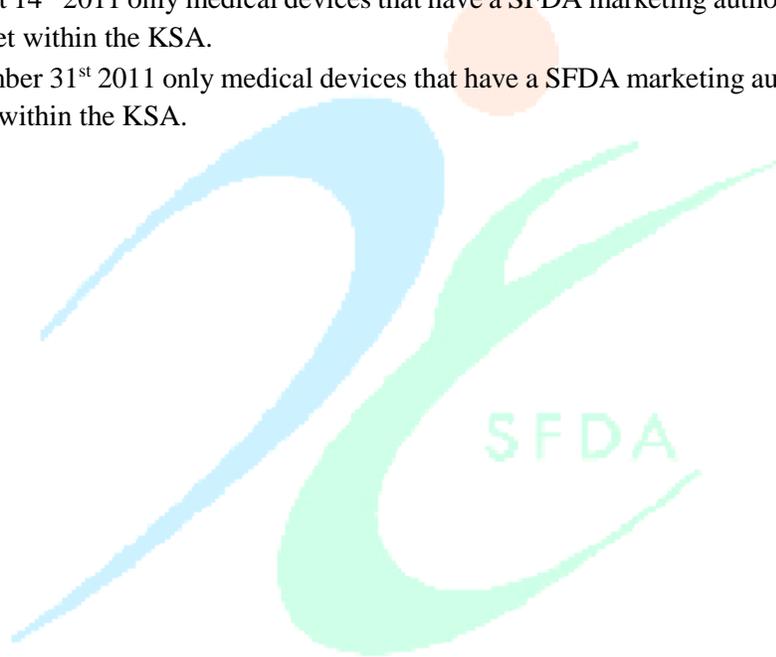
Article Eleven: Renewal or extension of marketing authorization

1. Prior to the marketing authorization expiring described in Article Ten, the local manufacturer or authorized representative, as appropriate, shall apply for either an extension, or renewal, of the authorization.
2. Extension applies where there has been no change to the device, in respect of safety or performance, since the authorization was previously issued. This procedure will apply when the authorization in the GHMF Founding Member jurisdiction on which the marketing authorization application was based has been updated without further technical evaluation of the device. Application for extension will be made through the MDMA.
3. In all other situations, the renewal procedure applies and updated documentation must be submitted through the MDMA.

Chapter Four General Provisions

Article Twelve: Application dates

- A. The Implementing Rule referred to in Article Five 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 this relates is February 14th 2011.
- C. Applications for a marketing authorization for medical devices may be made to the SFDA from the date referred to in paragraph B of this Article.
- D. From February 14th 2011 medical devices that have a SFDA marketing authorization may be placed on the market within the KSA.
- E. After August 14th 2011 only medical devices that have a SFDA marketing authorization may be placed on the market within the KSA.
- F. After December 31st 2011 only medical devices that have a SFDA marketing authorization may be put into service within the KSA.



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/ Definition of Lay person	Edit	have formal training in a specific field or discipline.	have formal training in a relevant field or discipline.
Article Three	Add	-	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.
Article Three	Add	-	Healthcare provider: any party, governmental or private, provides healthcare services with KSA including health clinics.
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	Edit	Chapters Two and Six of the Medical Devices Interim Regulation require manufacturers wishing to supply a medical device in the KSA, to provide the SFDA with documentation that demonstrates compliance of the device with the provisions of the Interim Regulation and this Implementing Rule that apply to it, i.e. proof that the manufacturer is authorized to place the device on the market of one of the GHTF Founding Member jurisdictions and, additionally, that it complies with the specific Saudi requirements. This Implementing	C. Chapters Two and Six of the Medical Devices Interim Regulation require manufacturers wishing to supply a medical device in the KSA, to provide the required documents that show the medical device complies with the Medical Device Regulations of at least one of the GHTF Founding Member jurisdictions, and additionally with provisions specific to the KSA concerning labeling and conditions of supply and/or use. This Implementing Rule specifies and/or completes the

		Rule specifies and/or completes the provisions of the Medical Devices Interim Regulation in relation to marketing authorization process.	provisions of the Medical Devices Interim Regulation in relation to marketing authorization process. D. According to Article Six of the Medical Devices Interim Regulation, the SFDA may issue marketing authorization in accordance with provisions specified by the SFDA. SFDA shall publish, on its website, a guidance document to specify these provisions.
Article Five/A	Edit	application form available on the MDMA portion	application form available on the Medical Devices Marketing Authorization (MDMA) portion
Article Five/B	Edit	uniform application of Articles Six to Ten.	uniform application of Articles Six to Nine.
Article Five	Add	-	C. Manufacturers 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/G	Edit	complies with the regulations of a particular GHTF Founding Member jurisdiction as described in Article Seven.	complies with the regulations of the particular jurisdiction that has been selected as a basis of the application as described in Article Seven.
Article Six	Edit	as described in Article Eight.	as described on SFDA website.
Article Seven	Edit	Article Seven: Documentary evidence that the medical device complies with the regulations of a particular GHTF Founding Member jurisdiction	Article Seven: Information and documentary evidence
Article Seven	Edit	The applicant shall specify which of the GHTF Founding Member jurisdictions is the basis of its application for marketing authorization within the KSA and provide the SFDA with information and documentary evidence, as follows:	The applicant shall provide the SFDA with information and documentary evidence, as follows:

Article Seven	Add	-	F. A copy, in electronic form, of the advertising and marketing materials that will be used in the KSA, if any.
Article Eight (in the previous IR version ...)	Delete	<p>Article Eight: Documentary evidence that the medical device complies with the National Provisions of the KSA</p> <p>The applicant shall provide the SFDA with information and documentary evidence, as follows:</p> <p>A. A copy, in electronic form, of the labeling associated with the medical device that will be placed on the market of the KSA, i.e. both the labels affixed to the device and the instructions for use, and show that the text of the different elements of the labeling and their content take appropriate account of the intended use of the devices and the qualifications of the users in the KSA.</p> <p>B. Where the device is connected to an a/c power supply, confirm it is designed to operate with a 60 Hertz supply at nominal values of either 220 or 380 volts and is fitted with the appropriate a/c power connector and provides the required electrical safety conditions. Also, ensure that the device shall perform as intended when subject to the other environmental factors encountered in the KSA.</p> <p>C. A copy, in electronic form, of the manufacturer’s instructions to ensure the medical devices intended to be placed on the KSA market will be correctly handled, transported, stored, installed, maintained and disposed of and to provide information that allows</p>	-

		<p>users and other persons, as appropriate, to be trained in their proper handling ,storage, use and maintenance.</p> <p>D. A copy, in electronic form, of the advertising and marketing materials that will be used in the KSA, if any.</p> <p>E. An attestation that the medical device complies with the national provisions of the KSA’s Medical Devices Interim Regulation.</p>	
Article Eight	Edit	Article Nine	Article Eight
Article Eight	Edit	provided to the SFDA that relate to the original marketing authorization in the GHTF Founding Member jurisdiction shall be in English,	provided to the SFDA shall be in English,
Article Eight/B	Edit	technical documents that support its Declaration of Conformity that the medical device complies with the provisions of the medical device regulations. of a GHTF Founder Member jurisdiction.	technical documents that support its application.
Article Eight/D/2	Edit	comply with the regulation of the selected GHTF Founding Member jurisdiction and with the relevant specific Saudi provisions;	comply with the Medical Devices Interim Regulation.
Article Eight/F	Edit	information shall be in English and, where justified, in Arabic.	information shall be in English and, where the user is a lay person, in Arabic and English.
Article Nine	Edit	Article Ten	Article Nine
Article Nine/B	Edit	SFDA shall allocate each application with its associated documents to a CAB (Conformity Assessment Body), duly appointed to assist the SFDA, and ask it to verify that the medical device complies with the provisions specified in this Medical Devices Interim Regulation. It is not intended that the CAB repeats the work undertaken by the Regulatory Authority or certification bodies of	SFDA may allocate applications with their associated documents to a CAB (Conformity Assessment Body), duly appointed to assist the SFDA, and ask it to verify that the medical device complies with the provisions specified in the Medical Devices Interim Regulation.

		the GHTF Founding Member jurisdiction. However, it will inspect the documents and information provided to it and confirm to its own satisfaction that the such documentation is sufficient and applies to the medical device under review.	
Article Nine/C	Edit	the CAB determines the adequacy of the documentary evidence in support of the applicant’s attestation of conformity with the: 1. Specified regulations of a GHTF Founder Member jurisdiction. and 2. National provisions of the Medical Devices Interim Regulation.	The SFDA and/or CAB determine the adequacy of the documentary evidence in support of the applicant’s attestation of conformity with the Medical Devices Interim Regulation.
Article Nine/D	Edit	Where the evidence offered is inadequate, the CAB will ask the SFDA to request the applicant	Where the evidence offered is inadequate, the SFDA will request the applicant
Article Ten	Edit	Article Eleven	Article Ten
Article Eleven	Edit	Article Twelve	Article Eleven
Article Eleven/1	Edit	described in Article Eleven	described in Article Ten
Article Eleven/3	Edit	updated documentation must be submitted through the MDMA for verification by a CAB.	updated documentation must be submitted through the MDMA.
Article Twelve	Edit	Article Thirteen	Article Twelve