Medical Devices Interim Regulation

Issued by the Saudi Food and Drug Authority Board of Directors
decree number (1-8-1429) and dated 27 December 2008, and
amended by Saudi Food and Drug Authority Board of Directors
decree number (4-16-1439) dated 27 December 2017

The Interim was published in Umm Al-Qura Journal year (86)
issue number (4249) dated 17 April 2009

Version number: 2.0

Chapter One
General Rules

Article One

For the purpose of this Interim Regulation, the following definitions apply:

KSA: means the Kingdom of Saudi Arabia

SFDA: means Saudi Food and Drug Authority

The Board: the SFDA board of directors

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.

Accessory: means a product intended specifically by its manufacturer to be used together with a medical device to enable that medical device to achieve its intended purpose.

Advertising of medical devices: means any form of information, canvassing activity or inducement intended to promote the supply or use of medical devices.

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

Authorized Representative: 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.

CAB: means a conformity assessment body (third party), established within the KSA, independent of both the manufacturer and user of the medical device that is subject to assessment.

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.

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.

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.

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.

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.

In-vitro medical device: means a medical device, whether used alone or in combination, intended by the manufacturer for the in-vitro examination of specimens derived from the human body solely or principally to provide information for diagnostic, monitoring or compatibility purposes. This includes reagents, calibrators, control materials, specimen receptacles, software and related instruments or apparatus or other articles.

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 identification, technical description.
C. Information accompanying a medical device, related to its use, but excluding shipping documents.

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.

Medical Devices National Registry (MDNR): is the database of registered establishments and the medical devices they manufacture or import or distribute.

National Center for Medical Device Reporting (NCMDR): is an organization managing a database of information on safety and performance related aspects of medical devices and capable of taking appropriate action on any confirmed problems.

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.

Putting into service: means the stage at which a device has been made available to the final user as being ready for use for the first time in the KSA for its intended purpose.

Registrant: means any party established within the KSA required to provide information for establishment registration or medical device listing purposes.

Article Two

The purpose of this Interim Regulation is to:

A. Protect and maintain public health within the KSA by the implementation of provisions ensuring a high level of safety and health protection of patients, users and third parties with regard to the use of medical devices as it relates to their manufacture, supply and use during their lifecycle.
B. Mandate measures, and allocate responsibilities, to ensure that medical devices placed on the market and/or put into service within the KSA comply with all relevant provisions of the Interim Regulation.

Article Three

This Interim Regulation applies to the following parties and products:

A. Manufacturers, authorized representatives, importers and distributors.
B. All Medical Devices and their accessories that will be, supplied to the KSA market.
C. Contact lenses and laser surgical equipment for cosmetic rather than medical purposes, and their accessories.

Chapter Two
Supplying Medical Devices to the KSA Market

Article Four

Medical devices may be placed on the market and/or put into service only if they comply with the applicable provisions of this Interim Regulation, as signified by the SFDA issuing the manufacturer with a written marketing authorization. The SFDA may exempt any medical device and shall announce the exempt medical devices on its website taking into consideration the public interest.

Article Five

Accessories of medical devices shall, for the purpose of this Interim Regulation, be treated as if they are medical devices in their own right and shall comply with all relevant provisions of the Interim Regulation.

Article Six

To obtain marketing authorization, medical devices shall comply with the relevant regulatory requirements applicable in one or more of the jurisdictions of Australia, Canada, Japan, the USA and the EU/EFTA, and additionally with provisions specific to the KSA concerning labeling and conditions of supply and/or use. The SFDA may issue marketing authorization in accordance with provisions specified by the SFDA.

Article Seven

Any person located within the KSA who transforms or modifies a medical device on his own behalf, in a way that may affect safety, performance or intended use, shall have its modification properly assessed and obtain a marketing authorization from the SFDA prior to placing the modified device on the market and/or to putting the modified medical device into service for the first time. Such a person is considered the manufacturer of the modified or refurbished medical device and shall inform the original manufacturer of any such planned activities.

Chapter Three
Medical Devices National Registry (MDNR)

Article Eight

The SFDA shall institute and maintain a web-based Medical Devices National Registry (MDNR) that shall include establishment registration and medical device listing databases. This registration and listing scheme shall fulfil the following purposes:

A. To collect and maintain the information required for establishment registration and medical device listing under this Interim Regulation.
B. To establish and maintain a profile of the KSA medical devices market.
C. To provide information on establishments involved in the manufacture or the supply of medical devices intended for the KSA.
D. To provide information on medical devices that will be supplied to the KSA.

Article Nine

The provision of establishment registration and medical device listing information to the SFDA, and the subsequent assignment of registration and listing numbers, does not remove from the registrant its obligation to comply fully with the regulations that apply to it within the KSA.

Chapter Four
Registration and Listing Requirements

Article Ten

1. Manufacturers established within the KSA, authorized representatives, importers and distributors of medical devices, healthcare providers importing medical devices, and any party who is involved in importing medical devices shall:
   A. Register their establishments with the SFDA.
   B. List medical devices with the SFDA.
2. Healthcare providers importing medical devices shall use them only for their own facilities.

Article Eleven

When the manufacturer is located outside the KSA, he shall appoint an authorized representative to act on his behalf.

Article Twelve

A manufacturer located in the KSA or an authorized representative may, at the same time, act as the importer and/or distributor of medical devices.

Article Thirteen

A. The registrant shall before it is involved in the supply of any medical device to the market for the first time:
   1. Submit information for registration purposes.
   2. Provide the required medical device listing information to the MDNR.

B. Attest to their accuracy.

C. Update the data previously provided to the MDNR for establishment registration purposes annually, or as required by the SFDA, or within 10 calendar days of the occurrence of any significant change to the relevant information.

D. Update the information data previously provided to the MDNR for medical device listing purposes annually, or as required by the SFDA, or within 10 calendar days of the occurrence of any significant change to the relevant information.

Article Fourteen

A. The SFDA shall issue a national registry number for each establishment

B. The SFDA shall issue a listing number for medical devices.

Chapter Five
Establishment Licensing

Article Fifteen

A. Local manufacturers, as well as importers, distributors and authorized representatives shall apply for an establishment license for their establishments, their branches and their warehouses.
B. The applicant shall provide:
    1. The establishment national registry number assigned to it by the SFDA after registering with the MDNR;
    2. The category of medical devices the applicant intends to supply to the KSA, and the contact details for the manufacturer of the device;
    3. An attestation that the establishment has documentary evidence that it complies with the responsibilities specified in Article Sixteen;
    4. An indication of any change to the information submitted within 10 calendar days of the change.

Article Sixteen

The applicant shall:

A. Notify the manufacturer/s of the device/s listed in Article Fifteen (B), or his authorized representative/s, of his intention to place these devices on the market;
B. Ensure that medical devices are stored and/or transported under conditions specified by the manufacturer;
C. Ensure traceability of devices it supplies to the market and be involved in market surveillance of devices that have been put into service;
D. Ensure the labeling accompanies each medical device together with a copy of the marketing authorization and undertake to inform the SFDA if they are unable to fulfil these obligations.

Article Seventeen

The SFDA undertakes the following:

I. Licensing of parties wishing to conduct the following:
    1. Clinical investigation in order to place the medical devices on the market.
    2. Clinical evaluation for medical devices after placing them on the market.
II. Issuing the approval for conducting the following:
    1. Clinical investigations.
    2. Clinical evaluation.

Article Eighteen

The SFDA shall issue the applicant with an establishment license that is renewable annually when it determines that the application meets the requirements of the Interim Regulation.

Chapter Six
Medical Devices Marketing Authorization

Article Nineteen

A. The manufacturer or its authorized representative shall for the medical devices it wishes to place on the market of the KSA:
    1. 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.
    2. Provide the documents in the English language and where the documents provided are in a language other than English, a summary, or translation, of the document shall be provided to the SFDA in English.
    3. At the SFDA's request, translate the relevant part of the document where a summary is provided.
    4. Provide a Declaration of Conformity, written in English that clearly identifies to which medical devices the Declaration applies and attests that its medical device complies with the regulatory requirements of the relevant GHTF Founding Member jurisdiction and also complies with the national provisions of this Interim Regulation.
    5. Provide a copy of the labeling associated with the medical device, in English and/ or Arabic language, and ensure that the text of the different elements of the labeling and their content take account of the intended use of the devices and the qualifications of the users in the KSA.
    6. Provide information on any measures taken to accommodate the specific environmental and/or conditions of use encountered in the KSA, if any.
    7. Specify measures to ensure its medical devices are correctly stored, transported, installed and maintained in the KSA, and users can be trained in their proper use.
    8. Undertake to report to the SFDA's National Centre for Medical Device Reporting (NCMDR), any relevant adverse event of which it becomes aware, that involves the medical device.

B. The manufacture shall provide a copy of the written mandate that defines the designated responsibilities of the manufacturer's authorized representative, if applicable.

C. The SFDA may ask for additional technical documentation before reaching its decision if such is required but, where it does so, provide a justification for the request.

Article Twenty

The SFDA will examine the submitted documents to verify that the medical device complies with the relevant provisions of this Interim Regulation.

Article Twenty One

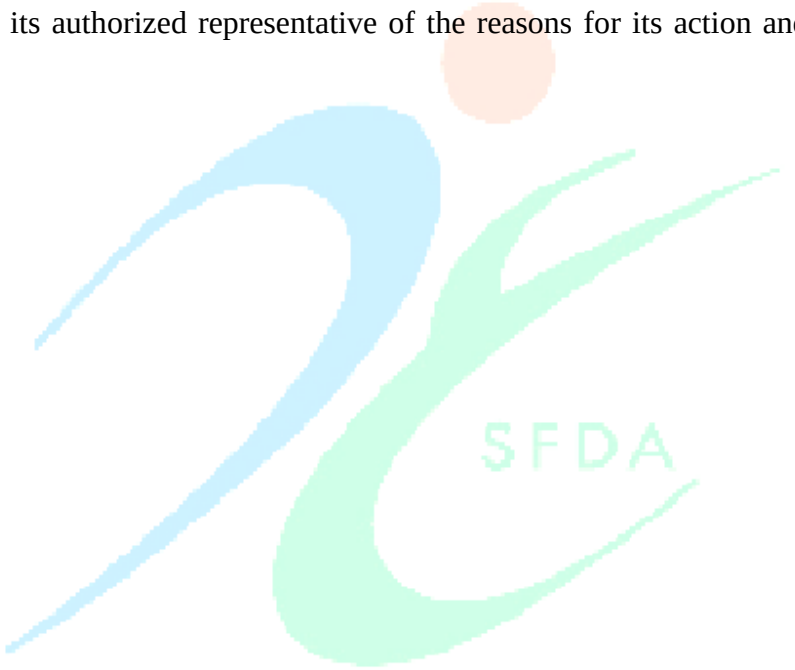
The SFDA shall issue a market authorization in writing to the manufacturer that permits the relevant medical devices to be placed on the market of the KSA, when satisfied that the manufacturer has provided all the required information for market authorization.

Article Twenty Two

The SFDA shall inform the applicant of the reasons for a decision not to issue a marketing authorization and of the means of appeal.

Article Twenty Three

The SFDA shall withdraw or suspend the marketing authorization where it detects or suspects a non-compliance with the relevant requirements of the Interim Regulation; and inform the manufacturer or its authorized representative of the reasons for its action and of the means for appeal.



Chapter Seven
The Conformity Assessment Bodies (CABs)

Article Twenty Four
While retaining in full the responsibilities placed upon it by the regulations, the SFDA may designate conformity assessment body (third party) to assist in carrying out some of its duties in this Interim Regulation.

Article Twenty Five
The SFDA is responsible for designating CABs for specific tasks.

Article Twenty Six
Duties of Conformity Assessment Bodies:

A. Examine the documents submitted for medical device market authorization purposes.
B. Ensure that the medical device complies with the relevant provisions of this Interim Regulation.
C. Recommend to the SFDA that it may issue the marketing authorization.
D. Any other duties within their area of competence that the SFDA may wish to delegate to them.

Article Twenty Seven
The SFDA shall monitor the performance of the CABs.

Article Twenty Eight
The designated CAB, its Director and the assessment and verification staff shall not be the designer, manufacturer, supplier, installer or user of the devices which they inspect, nor the authorized representative of any of these persons. They may not be involved in the design, construction, marketing or maintenance of the devices, nor represent the parties engaged in these activities.

Article Twenty Nine
The impartiality of the designated CABs must be guaranteed.

Chapter Eight
Post-Market Surveillance of Medical Devices

Article Thirty
The SFDA shall take all appropriate measures to ensure medical devices placed onto the market of the KSA comply with the requirements of this Interim Regulation.

Article Thirty One
The local and overseas manufacturers, authorized representatives, importers and distributers of medical devices, and healthcare providers importing medical devices shall apply a quality management system. The SFDA will publish the requirements for the quality management system on its website, and will ensure their compliance to these requirements.

Article Thirty Two
Where the SFDA has reason to believe a manufacturer, an authorized representative or another party in the supply chain of a medical device has made a misleading or fraudulent claim of the medical device, it shall investigate and take action as appropriate to the circumstances.

Article Thirty Three
If during its market surveillance activities, the SFDA comes across a noncompliance that has implications for public health, it shall alert patients, users or other persons, as appropriate.

Article Thirty Four
The SFDA shall institute and maintain a web-based National Centre for Medical Device Reporting (NCMDR) to fulfil the following purposes:

A. Improve protection of the health and safety of patients, users and others.
B. Disseminate relevant device related information which may reduce the likelihood of, or prevent repetition of adverse events, or alleviate consequences of such repetition.
C. Execute a key aspect of the SFDA's post-market activities.
D. Encourage collaboration between manufacturers and health care facilities to identify and investigate adverse events associated with medical devices and take appropriate action.
E. Encourage the reporting of adverse events by medical device institutions and users, manufacturers, authorized representatives and organizations involved in supplying medical devices to the KSA.
F. Provide a database of information on the safety and performance of medical devices that is suitable for the exchange of adverse events information with other Regulatory Authorities.

Article Thirty Five

The SFDA shall review adverse events reported to its NCMDR and take appropriate action to safeguard public health.

Article Thirty Six

The SFDA shall establish a mechanism to issue Field Safety Notices to medical device users and, where relevant, patients. Before issuing such a Notice, its text shall be discussed with the organizations responsible for manufacturing the device and supplying it to the KSA.

Article Thirty Seven

The SFDA shall monitor the use of medical devices in the KSA and take the appropriate measures to ensure their proper installation and maintenance in respect of the safety of patients, users and other persons.

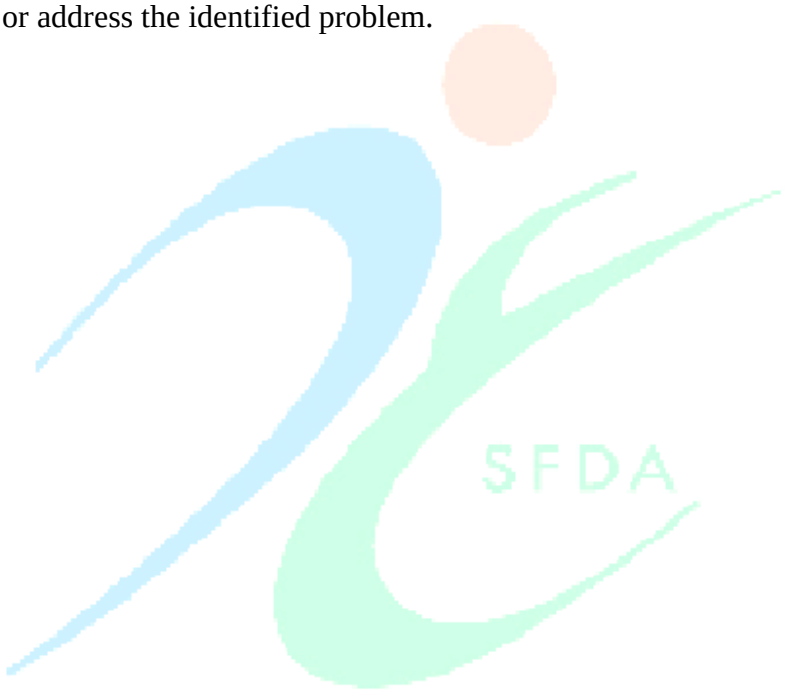
Chapter Nine
Safeguard Activities

Article Thirty Eight

Where the SFDA has evidence to suggest that the health and/or safety of patients or users is compromised despite the medical device having been lawfully supplied to the market of the KSA, it reserves the right to require the device to be withdrawn, or restricted in some manner.

Article Thirty Nine

Any such action will be justified to the manufacturer, authorized representative, importer, distributor and user, as appropriate, in writing, together with information of the procedure to appeal the action taken or address the identified problem.



Chapter Ten
General Provisions

I. Confidentiality of Information

Article Forty

For the purpose of information security and confidentiality, the following shall apply:

A. All the parties involved in this Interim Regulation are bound to observe confidentiality with regard to all relevant information obtained in carrying out their tasks.
B. This does not affect the obligation of the SFDA and any designated CABs to exchange information among themselves.
C. This does not affect the SFDA's obligation with respect to the dissemination of warnings or guidance that assist in the safeguarding of public health,
D. This does not affect the obligations of the persons concerned to provide information under criminal law.

I I. Advertising

Article Forty One

A. The advertising of a medical device for which the SFDA has not issued a marketing authorization is prohibited.
B. All advertisement material must be approved by SFDA.
C. The advertising material shall not mislead the user regarding the performance of the medical device as specified by the manufacturer.
D. The advertising to the general public, including on the internet, shall avoid misleading lay persons.
E. Any advertising to persons qualified to use medical devices shall include the relevant information compatible with their specific needs.
F. Medical sales representatives shall have sufficient knowledge to be able to provide appropriate information about the medical devices they promote.

Chapter Eleven
Conclusion Measures

Article Forty Two

The SFDA reserve the right to take the appropriate actions when any of the interim measures are violated, such as:

A. Suspend the license.
B. Terminate the license.
C. Recall the product from the market.
D. Withdrawal of the marketing authorization.

Article Forty Three

SFDA shall publish a list for medical devices marketing authorization fees.

Article Forty Four

The fee for the medical device establishment license shall not exceed thirty five thousand Riyals (35,000 SR), and should be based on each establishment's category.

Article Forty Five

SFDA shall adopt and publish Implementing Rules to specify the provisions of this Interim Regulation. Each implementing rule shall specify its application date and the application date of the provisions of the interim regulation to which it relates.

Article Forty Six

Applications for market authorization will be accepted sixty days after publication of the Implementing Rule for chapter six.

Article Forty Seven

This Interim Regulation shall be published in the official journal and applies 90 days after its publication.