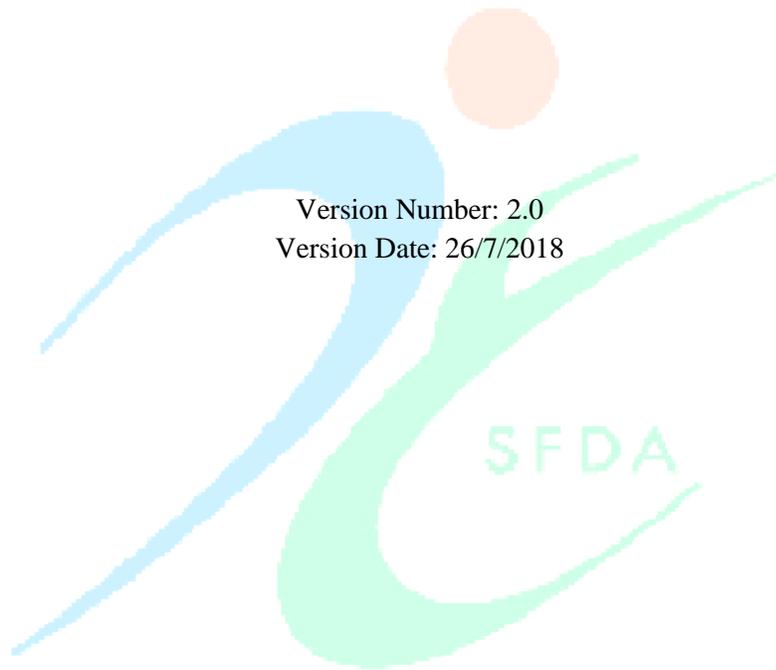


MDS-IR8

Implementing Rule on  
Safeguard Procedures

Version Number: 2.0  
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 (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 Nine in relation to measures to be taken against medical devices that have been placed on the market of the KSA, where a serious public health risk may exist. It is also intended to ensure the uniform application of the relevant requirements by all the parties involved.

### Article Three: Definitions

For the purpose of this Implementing Rule 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.

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

**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.

**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.

**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.

**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.

**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.

**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.

**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.

**User:** means the health care institution, professional or patient using and /or maintaining medical devices.

**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.

**Authorizing GHTF CA:** means the Competent Authority of the GHTF Founding Member country or jurisdiction that forms the basis of a manufacturer's application for marketing authorization within the KSA.

**NCA:** means the National Competent Authority responsible for medical device regulations within that country.

**National Competent Authority Report (NCAR):** means a report received from GHTF National Competent Authority members concerning a medical device related adverse event and recalls.

**Safety Alert Dissemination System (SADS):** means a report from AHWP National Competent Authority members concerning a medical device related adverse event and recalls.

**National Centre for Medical Device Reporting (NCMDR):** means an organization managing a database of information on safety and performance related incidents with medical devices and capable of taking appropriate action on any confirmed problem.

**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.

**Corrective action:** means an action to eliminate the cause of potential nonconformity or other undesirable situation.

**Field safety corrective action:** means an action taken by a manufacturer to reduce or remove a risk of death or serious deterioration in the state of health associated with the use of a medical device that is already placed on the market.

**Field safety notice:** means a notification from the SFDA to relevant medical device users in relation to a Field Safety Corrective Action.

**Harm:** means physical injury or damage to the health of people or damage to property or the environment.

**Adverse Event:** means any malfunction or deterioration in the characteristics and/or performances of a medical device, including any inadequacy in its labeling or the instructions for use which may lead to compromise the health or safety of patients, users or third parties.

**Reportable Adverse event:** means any adverse event or any technical or medical reason leading to a Field Safety Corrective Action, which, directly or indirectly, might lead to or may have led (a) to the death of a patient, a user or another person or (b) to a serious deterioration in their state of health.

**Serious public health threat:** means any event type, which results in imminent risk of death, serious injury, or serious illness that may require prompt remedial action.



## Chapter Two

### Safeguard Measures

#### **Article Four: Actions to safeguard public health**

- A. Where the SFDA acquires information that a medical device made available on the market within the KSA does not comply with the relevant provisions of the Medical Devices Interim Regulation and/or its Implementing Rules it shall ensure that local manufacturers or importers and distributors take appropriate action to remove any threat to public health. Such information may come from:
1. The SFDA's own market control activities, as described in Article 9 of the Implementing Rule MDS-IR 7 on Post Marketing Surveillance, may indicate the medical device non-compliances that may affect its safety and performance or administrative infringements such as:
    - Medical device is not accompanied by the relevant declaration of conformity;
    - Accompanying declaration of conformity is not properly drawn up;
    - Appropriate technical documentation is not available or has not been made available within a reasonable period of time
  2. Information provided by any organization involved in either importation or distribution activities , who is required to inform the SFDA , if it believes a medical device it imports or distributes does not comply with the Medical Devices Interim Regulation and/or its Implementing Rules , as required by Article 10 of Implementing Rule MDS – IR7 on Post-Marketing Surveillance .
  3. Information provided by a manufacturer, as a result of its vigilance activities, that a medical device it manufactures for the KSA market, has caused a reportable adverse event.
- B. If the actions referred to in paragraph 1 to remove any threat to public health are not or cannot be taken in due time or if the SFDA decides there is a need to supplement them, it shall take a safeguard measure.
- C. Where necessary, the SFDA's safeguard measure may include the issuing of a field safety notice to medical device users and/ or hospital authorities, warning them that there is a public health threat associated with the use of the medical device, describing the risks involved in continuing to use the medical device and advising them to withdraw the medical device from use immediately, unless the clinical benefit of continuing to use the medical device is judged to outweigh the harm it might do.
- D. The SFDA shall ensure that any measure it takes against nonconforming medical devices is proportionate to the risk to public health and shall communicate the exact grounds for its actions to all the parties concerned. Such measures could include the temporary suspension of the medical devices authorization, immediate correction of the administrative infringement, the implementation by the manufacturer of an agreed corrective action plan.
- E. Prior to the adoption of a measure referred to in paragraphs (C) or (D) of this Article, the local manufacturer, authorized representative, importer and distributor, as relevant, shall be given the opportunity to be heard within an appropriate period of time taking into account the urgency of the measure to be taken.
- F. The measure selected by the SFDA shall be communicated without delay to the local manufacturer or to the importer, distributor and authorized representative, as relevant, which shall at the same time be informed of the remedies available under KSA law and of the time limits to which such remedies are subject.

- G. After a safeguard measure has been taken, the SFDA shall ask the medical device manufacturer, through the authorized representative where applicable, to investigate the information which caused it to act.
- H. The SFDA shall inform the authorizing GHTF Competent Authority concerned about the measures it has taken. It shall supply all available details, in particular, the information necessary for the identification of the non-compliant medical device, its manufacturer, the nature of the alleged noncompliance and of the serious public health threat, the nature and the duration of the measure taken and any contradictory evidence provided by the manufacture, the importer or distributor.
- I. The SFDA will ask the authorizing GHTF CA to inform it of any additional information it has that may be relevant to its investigation. It shall also ask to be informed of the outcome of the authorizing GHTF CA's investigation of the medical device.
- J. After receiving the manufacturer's report and the results of the investigation performed by the authorizing GHTF CA, the SFDA shall decide whether the safeguard measure shall be maintained. The SFDA shall issue a second field safety notice to provide medical device users and/or hospital authorities, indicating the outcome of its further investigations.
- K. The SFDA shall ensure that the safeguard measures it has taken to eliminate the risk are fully implemented by all parties concerned.
- L. The SFDA shall adopt and publish a guideline(s) to ensure a coherent and uniform application of this Article.

**Article Five: Actions to safeguard public health where a medical device has been lawfully placed on the KSA market**

- A. Occasionally, a new hazard emerges that was unappreciated by the manufacturer when it designed the medical device and completed a risk assessment. In this situation, the SFDA shall evaluate the evidence and consider whether it needs to take the safeguard actions described in Article Four.
- B. The SFDA shall consult with other NCAs since hazards of this type will not be restricted to medical devices placed on the KSA market.

## Chapter Three Global Responsibilities

### **Article Six: Global aspects**

- A. As required in Article Four paragraphs (H) and (I), the SFDA shall inform the authorizing GHTF Competent Authority concerned of the measures it has taken and shall take account of the outcome of the authorizing GHTF CA's investigation of the medical device.
- B. Where the investigation by the GHTF Founding Member confirms there is a serious public health threat, the SFDA shall, in cooperation with the authorizing GHTF CA, communicate that finding to other National Competent Authorities.
- C. As a member of the NCAR Reporting Programme and SADS, the SFDA shall fulfil its membership responsibilities according to the programme's operating procedures.

## Chapter Four General Provisions

### **Article Seven: 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 1<sup>st</sup> September 2010.

SFDA

## 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 Two	Edit	The present Implementing Rule, in accordance	This Implementing Rule, in accordance
Article Three/ Definition of Global Harmonization Task Force (GHTF)	Edit	Global Harmonization Task Force (GHTF): means the countries working to achieve harmonization in medical device regulation among themselves.	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.
Article Four/D	Edit	could include the temporary suspension of the medical devices marketing authorization,	could include the temporary suspension of the medical devices authorization,

SFDA