

MEDICAL DEVICES SECTOR

MDS - IR1

IMPLEMENTING RULE ON DESIGNATION AND OVERSIGHT OF CONFORMITY ASSESSMENT BODIES

Application Date: January 4th 2010

Version 2

Our mission is to ensure the safety of food; the safety, quality and efficacy of drugs; and the safety and effectiveness of medical devices, by developing and enforcing an appropriate regulatory system.

SFDA

Our mission is to ensure safety, effectiveness and quality of medical devices and their performance according to their intended purpose and to ensure the safety of related electronic products.

SFDA
Medical Devices Sector

Implementing Rules specify requirements which refine and/or specify the provisions of the Medical Devices Interim Regulation and they have force of law. Their application takes part in ensuring that medical devices placed on the KSA market achieve an appropriate level of safety and performance with regard to their manufacture, supply and use. Please refer to the SFDA Medical Devices Interim Regulation, published in the Umm Al-Qura Journal year 86 Issue No. 4249 dated 17 April 2009, for the general provisions and in SFDA

website: <http://www.sfda.gov.sa/En/MedicalEquipments/Topics/interim+E.htm>.

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Table of Contents

CHAPTER ONE	General Rules	1
CHAPTER TWO	Application for Designation as a CAB under the Medical Devices Interim Regulation	4
CHAPTER THREE	Responsibilities of the SFDA	6
CHAPTER FOUR	Responsibilities of the Conformity Assessment Body	7
CHAPTER FIVE	General Provisions	11

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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 43 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 Seven in relation to the responsibilities, competence and governance of the Conformity Assessment Bodies.

Article Three

For the purpose of this Implementing Rule the following definitions apply:

KSA: means the Kingdom of Saudi Arabia.

SFDA: means 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.

Audit: means systematic, independent, documented process for obtaining records, statements of fact or other relevant information and assessing them objectively to determine the extent to which specified requirements are fulfilled.

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.

Conformity Assessment Body (CAB): means a 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.

Global Harmonisation Task Force (GHTF): means 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.

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.

Article Four: General Principles

- A. The Medical Devices Interim Regulation requires the SFDA to examine the evidence submitted by manufacturers and/or their Authorized Representatives wishing to market medical devices within the KSA in order to verify that the medical device complies with the provisions specified in this Interim Regulation. The SFDA may ask for additional technical documentation before reaching its decision but, where it does so, must justify such a request. When satisfied that the manufacturer has provided all the information required, the SFDA shall issue a market authorization in writing that permits the relevant medical device(s) to be placed on the market of the KSA.
- B. While retaining in full the responsibilities placed upon it by the regulations, the SFDA may designate third-party organizations, known as Conformity Assessment Bodies (CABs), to assist it in carrying out its duties.
- C. This Implementing Rule specifies and/or completes the provisions of the Medical Devices Interim Regulation in relation to the responsibilities, competence and governance of such CABs¹.

¹Chapter Seven of the Interim Regulation.

Chapter Two: Application for Designation as a CAB under the Medical Devices Interim Regulation

Article Five

CABs shall be established in KSA, to review and evaluate, on behalf of the SFDA, the adequacy of the documentation provided to the SFDA by the manufacturer or its authorized representative in order to obtain a market authorization under the requirements of the Medical Devices Interim Regulation and its Implementing Rules.

Article Six

Each candidate CAB shall apply to the SFDA in writing for designation as a CAB and shall provide to it the following information.

- A. The name and contact details (i.e. postal address in a format that allows location to be established, telephone number and e-mail address) of the registered place of business of the candidate CAB, and of its parent organization, together with contact persons at both locations.
- B. A description of the organizational structure and management of the CAB and its relationship to other parts of the parent and any subsidiary organization. Information shall be provided on the qualifications, duties, responsibilities, and authorities of management and other employees of the CAB, as they relate to the Medical Devices Interim Regulation.
- C. A description and organization chart to illustrate the professional relationship between the employees located at the CAB and those located outside the KSA, in particular, those based with the parent organization.
- D. Details on the procedures, processes and resources to be applied by the CAB in preparing the evaluation reports.
- E. Information on the CAB's and parent organization's experience of medical device marketing authorization procedures in one or more of the following jurisdictions: Australia, Canada, EU/EFTA, Japan and the

USA; and the categories of medical device to which such experience extends.

- F. Details of the CAB's liability insurance arrangements.
- G. Details of the CAB's legal status under KSA law.
- H. Details of the CAB's policy and arrangements to safeguard the confidentiality of the information obtained or created during the performance of its duties.
- I. Details of the CAB's policy and arrangements to ensure its management and employees will carry out their duties in an independent, objective, ethical and impartial manner, and will avoid any conflicts of interest.
- J. A description of the CAB's quality management procedures.
- K. An attestation that the CAB has implemented the policies and procedures described in (H), (I) and (J), above, and an undertaking to maintain the number, qualifications and experience of its employees at a level sufficient to allow proper functioning of the CAB.

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Chapter Three: Responsibilities of the SFDA

Article Seven:

The SFDA is responsible for:

- A. Appointing CABs with responsibilities under the Medical Devices Interim Regulation
- B. Reviewing the documents provided to ensure that each CAB it appoints is impartial and seeks to attain the highest degree of professional integrity, and that the CAB's employees have the requisite competence in the field of medical devices and are free from all pressures and inducements, particularly financial, which might influence their judgement.
- C. Ensuring that the CAB has experience with respect to the medical device regulation of one or more of the GHTF Founding Member countries and designating it accordingly.
- D. Allocating tasks to each CAB in respect of the applications it receives from manufacturers for authorization to supply a medical device to the market of the KSA.
- E. Charging a medical device manufacturer, or its authorized representative, for the work undertaken by the SFDA and CAB, to evaluate the documentation provided to it to support the marketing authorization application.
- F. Agreeing with each CAB the payments it shall make in respect of an evaluation.
- G. Monitoring and auditing the performance of CABs.
- H. Ensuring each CAB has, and retains, the competences required of it to carry out allocated tasks.
- I. Publishing a list of the designated CABs.

Chapter Four: Responsibilities of the Conformity Assessment Body

Article Eight: Resources

- A. The CAB shall provide the resources for the requested evaluation of the documents submitted for the medical devices as specified in the Medical Devices Interim Regulation in a competent, transparent, neutral, independent and impartial manner. Adequate resources shall be provided and committed in terms of competent employees, supervision, financial support, sufficient time to conduct effective evaluations and, where necessary, access to technical information and expertise from external sources, in order to ensure that the conclusions reached are reliable.
- B. Once designated, the CAB shall, without delay, inform the SFDA of any change regarding availability of resources, and compliance with designation conditions which may have an impact on the maintenance of the designation and of the assignment of tasks.
- C. Employees involved in conformity assessment evaluations shall have general experience of medical devices, and shall possess relevant education, skills and experience with respect to the medical device regulations of at least one of the GHTF Founding Member jurisdictions. They shall also have knowledge of the requirements of the Medical Devices Interim Regulation and its Implementing Rules
- D. Employees involved in conformity assessment evaluations shall have access to other persons possessing relevant education, skills and experience of:
 - 1. The assessment of risk analysis and risk management evaluations for medical devices.

2. The assessment of medical function and performance of medical devices.
 3. The assessment of clinical evaluation reports.
- E. Where the CAB uses a team of employees to undertake an evaluation, rather than a single person, such competencies must be present within the team as a whole but not necessarily by each member.
- F. The CAB shall maintain a record of persons involved in each evaluation, including those based outside the KSA. This record should be made available to the SFDA upon request.

Article Nine: Independence and impartiality

The activities of the CABs, its parent and any subsidiary organization, shall ensure impartial advice is provided to the SFDA regarding the CAB's evaluation of a manufacturer's market authorization application made under the Medical Devices Interim Regulation. To ensure this outcome:

- A. Employees shall be impartial and free from engagements and influences which could affect their objectivity, and in particular, for a medical device that is the subject of a market authorization application, shall not:
1. Be involved in the design, construction, marketing, installation, servicing or supply of that medical device.
 2. Be involved in the design, implementation or auditing of the manufacturer's quality management system.
 3. Have been involved in the provision of consultancy services in respect of the medical device.

4. Have participated in obtaining market access of the device to the GHTF Founder Member jurisdiction that forms the basis of the manufacturer's market authorization application under the Interim Regulation.
 5. Be an authorized representative of the manufacturer of the medical device.
- B. Employees with responsibilities for any part of the conformity assessment evaluation shall not have a financial interest in the manufacturer, importer or distributor of the medical device.
 - C. The impartiality of the CAB and the employees involved in evaluations shall be established and documented. This will include any declaration and/or identification and investigation of potential conflict of interests, together with the outcome of any such investigation.
 - D. The CAB shall indicate any potential conflict of interest to the SFDA upon receipt of a task allocated to it by the SFDA under the provisions of this Interim Regulation.

Article Ten: Confidentiality and due professional care

- A. The confidentiality of all documents and information obtained shall be safeguarded. There shall be no disclosure of such documents and information to any other party other than the SFDA, without the explicit approval of the manufacturer concerned.
- B. Due professional care, diligence and good judgment shall be practiced at all times in the conduct of an evaluation, and in the management of supporting activities, in accordance with a documented procedure.
- C. The CAB shall have and document a policy and arrangements to safeguard the confidentiality of the information obtained or created during the performance of an evaluation.

- D. The CAB shall inform the SFDA of all available information it has obtained which may be useful in the execution of SFDA's responsibilities.

Article Eleven: Quality management procedure

- A. The CAB shall implement and maintain a quality management procedure to ensure that the evaluations it conducts satisfy the requirements of the Medical Devices Interim Regulation. This procedure shall cover, as a minimum, control of documents, control of records, management review, internal audits, and corrective and preventive actions.
- B. The quality management procedure must ensure that evaluations are performed in accordance with defined and documented methodologies and techniques designed to provide consistency of approach and depth among evaluations of the same type and scope.

Article Twelve: Legal requirements

- A. The CAB shall be a legal entity under KSA law, or a defined part of a legal entity, such that it can be held legally responsible for all its activities in the KSA, including the decisions it makes.
- B. The CAB shall have a registered place of business within the KSA.

Article Thirteen: Liability insurance

The CAB shall have appropriate liability insurance to provide for any claims and litigation arising from its operations.

Chapter Five: General Provisions

Article Fourteen: Application form

The applicant CAB shall fill in the application form presented on the dedicated SFDA website and send it to the SFDA for evaluation together with the supporting documentation to demonstrate compliance with the relevant provisions of the Medical Device Interim Regulation and the present Implementing Rule.

Article Fifteen: Application date

- A. This Implementing Rule and the corresponding application forms referred to in Article Fourteen 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 April 1st 2010.
- C. Applications to the SFDA may be submitted from the application date referred to in paragraph B of this Article.

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