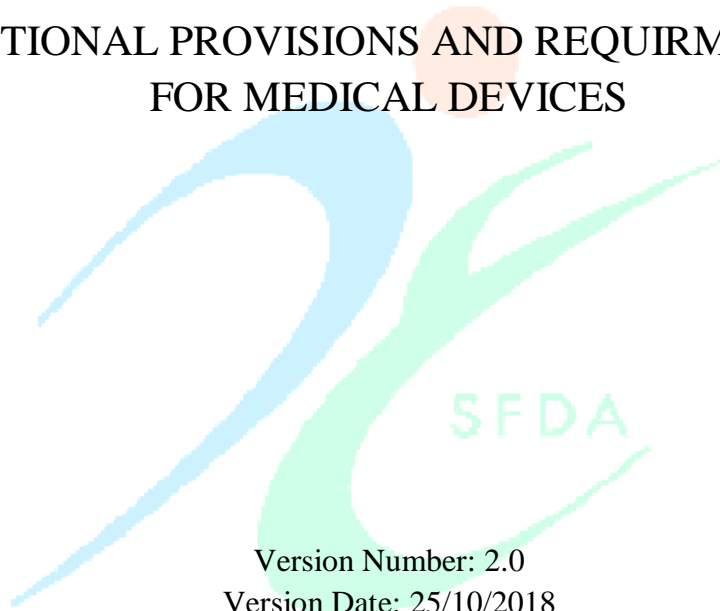


# NATIONAL PROVISIONS AND REQUIREMENTS FOR MEDICAL DEVICES



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These provisions and requirements have been published after being distributed for public comments on 08/06/2017 for 90 days.

## Article One

SFDA/MDS has issued these provisions and requirements in reference to article six of the Medical Devices Interim Regulation that stipulating provisions specific to the KSA concerning labeling and conditions of supply and/or use.

## Article Two

For the purpose of this document, the following definitions shall apply:

KSA	Kingdom of Saudi Arabia
SFDA	Saudi Food and Drug Authority
MDMA	Medical Devices Marketing Authorization
SASO	Saudi Standards, Metrology and Quality Organization
ISO	International Organization for Standardization
IEC	International Electrotechnical Commission
SBC 401	Saudi Building Code –Electrical Requirements
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 (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.
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.
Instructions For Use (IFU)	means information provided by the manufacturer to inform the device user of the medical device’s intended purpose and proper use and of any precautions to be taken.
Lay Person	individual that does not have formal training in a relevant field or discipline.

Medical Device	<p>means any instrument, apparatus, implement, machine, appliance, implant, in vitro reagent or calibrator, software, material or other similar or related article:</p> <p>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:</p> <ul style="list-style-type: none"> <li>- diagnosis, prevention, monitoring, treatment or alleviation of disease,</li> <li>- diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap,</li> <li>- investigation, replacement, modification, or support of the anatomy or of a physiological process,</li> <li>- supporting or sustaining life,</li> <li>- control of conception,</li> <li>- disinfection of medical devices,</li> <li>- providing information for medical or diagnostic purposes by means of in vitro examination of specimens derived from the human body;</li> </ul> <p>and</p> <p>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.</p>
Medical Electrical Equipment	<p>any electrical equipment having an applied part or transferring energy to or from the patient or detecting such energy transfer to or from the patient and which is:</p> <ul style="list-style-type: none"> <li>a) provided with not more than one connection to a particular supply mains; and</li> <li>b) intended by its manufacturer to be used: <ul style="list-style-type: none"> <li>1. in the diagnosis, treatment, or monitoring of a patient; or</li> <li>2. for compensation or alleviation of disease, injury or disability</li> </ul> </li> </ul>
Home Use Medical Device	<p>is a medical device labelled for use by users in any environment outside of healthcare facility. This includes but not limited to office environments, schools, and vehicles. If the medical device is intended to be used in healthcare facilities and outside those facilities, it meets this definition.</p>

### **Article Three**

The purpose of provisions and requirements is to specify and clarify the provisions and requirements specific to the KSA of medical devices intended to be placed on the market and put into service. The national provisions and requirements concern:

- Electrical medical devices
- Quality Management System
- Home use medical devices
- Labeling
- Manufacturer's instructions
- Environmental factors
- Measurement units
- Imaging medical devices
- Sunglasses
- Medical gas cylinders

### **Article Four**

These provisions and requirements apply 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.

### **Article Five**

Manufacturers, authorized representatives, importers and distributors shall apply a quality management system (QMS) in accordance with SFDA requirements for medical devices QMS.

### **Article Six**

For electrical medical devices, colours of conductors' insulators shall be in accordance with the Saudi Building Code –Electrical Requirements part 401 of SBC and the Saudi standard entitled "Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (SFDA.MD/IEC 60601-1)".

## **Article Seven**

Where the electrical medical device is intended to be connected to an a.c. power supply, manufacturer shall confirm the following:

- A. The device is designed to operate with a 60 Hertz supply at nominal values of either 230 or 400 volts.
- B. The device is fitted with the appropriate a/c power connector in accordance with part 401 of SBC and the Saudi standard entitled "Plugs and socket-outlets for household and similar purposes- safety requirements and test methods 250 V/13 A (SASO-2203)".

## **Article Eight**

For home use medical devices, if the user is a lay person:

- A. The label (including that on any display) and IFU shall be, wherever feasible, in both Arabic and English languages. Where this is not feasible, the language shall be Arabic.
- B. The IFU shall be provided in a paper format.
- C. The advertising and marketing material shall be provided in both languages (Arabic and English).

## **Article Nine**

For home use medical devices, label and/or IFU shall:

- A. Contain contacts information for the center(s) within the KSA providing technical assistance for users.
- B. Be supplemented by machine-readable forms, such as radio-frequency identification (RFID) or bar codes.
- C. Be written in a simple language to indicate the safe use of the medical device and all of its functions, and shall contain all necessary information and precautions.

## **Article Ten**

Label and IFU shall contain an indication of any special storage and/or handling conditions that apply (e.g., when the device needs to be stored, operated, transported or used in temperatures specified by the manufacturer).

### **Article Eleven**

Label shall contain an unambiguous indication of the date until when the medical device may be used safely (e.g., on medical devices supplied sterile), where this is relevant.

### **Article Twelve**

Manufacturer's instructions for handling, storage, transportation, installation, maintenance (including service manuals), and disposal of the medical devices shall be made available to the SFDA or any relevant party in English and, when requested, in Arabic.

### **Article Thirteen**

Manufacturer shall ensure that the medical device will maintain its specified performance and will perform as intended when subject to the environmental and/or conditions of use that may be encountered within the KSA. The IFU and label shall provide information on any measures taken to accommodate those conditions, such as local temperature and humidity conditions for operating, transportation and storage.

### **Article Fourteen**

For medical devices incorporating a measuring function, measurements units shall be expressed in SI international system of units according to the Saudi Metrology Law.

### **Article Fifteen**

Imaging medical devices shall be capable of automatically recording dose, protocol data, and patient information such as age, gender and weight in standardized formats.

### **Article Sixteen**

Sunglasses shall comply with SFDA requirements and standards for ultraviolet radiation protection.

## Article Seventeen

Gas cylinders for medical use shall bear the colour(s) corresponding to the gas(es) they contain in accordance with the the Saudi standard entitled “Gas cylinders for medical use – marking for identification of content (SFDA.MD/ISO 32)”, and it shall be applied in such a manner that is visible at the valve end. The following table clearly identifies the gas names and colours.

Gas Names and Identification Colours

Name of Gas	Formula/ Symbol	Colour
Oxygen	O <sub>2</sub>	White
Nitrous Oxide	N <sub>2</sub> O	Blue
Cyclopropane	C <sub>3</sub> H <sub>6</sub>	Orange
Carbon Dioxide	CO <sub>2</sub>	Grey
Ethylene	C <sub>2</sub> H <sub>4</sub>	Violet
Air	-	White and Black
Helium	He	Brown
Nitrogen	N <sub>2</sub>	Black
Oxygen and Carbon Dioxide	O <sub>2</sub> + CO <sub>2</sub>	White and Grey
Oxygen and Helium	O <sub>2</sub> + He	White and Brown
Oxygen and Nitrous Oxide	O <sub>2</sub> + N <sub>2</sub> O	White and Blue