

# MDS - G2

## GUIDANCE FOR LOCAL MANUFACTURERS

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## PART I

### Preparing for Medical Device Marketing Authorization

#### A. Registration Requirements

*Exert from CHAPTER FIVE of the **MEDICAL DEVICES INTERIM REGULATION***

##### **Article Ten**

**Manufacturers established within the KSA**, authorized representatives, importers and distributors of medical devices shall:

- A. Register their establishments with the SFDA.

##### **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 Medical Devices National Registry (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.

## Article Fourteen

- A. The SFDA shall issue a National Registry Number for each establishment.

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## *Exerts from Implementing Rule MDS-IR 2 Establishment Registration*

## Article Eight

For the purposes of registration, and irrespective of device classification, each registrant shall complete the relevant electronic application form available on the MDNR and thereby submit the following information to the SFDA:

- A. An indication whether the registrant is a local manufacturer, an authorised representative, an importer or a distributor of medical devices intended to be supplied to the KSA market and a description of its activities related to manufacturing and/or importation and/or distribution.
- B. 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 place of business of the registrant together with the name and position held of the person responsible for the registration within that organization.
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- E. An indication that the information provided is either a new entry or an update of previously submitted information. If the second situation applies, the establishment National Registry Number allocated to the registrant shall be provided.
- F. The date when the information is submitted.

**Article Nine:**

The SFDA is responsible for:

- D. Assigning an establishment National Registry Number to each registrant.

**Article Ten:**

The registrant is required to :

- B. Attest to its accuracy.
- C. Update the information provided within 10 calendar days of the occurrence of any change or when requested to do so by the SFDA, in order to maintain the accuracy of the registration information.

**COMMENTS**

1. Each **local manufacturer** (i.e. a medical device manufacturer located within the KSA) requires an Establishment National Registry Number from the SFDA/MDS. The application for registration will be made electronically through the Medical Device National Registry (MDNR) which is found on the SFDA website and, together with Implementing Rule MDS-IR2 Establishment Registration, prescribes the information that has to be provided before the SFDA/MDS assigns the local manufacturer a National Registration Number.
2. The **local manufacturer** shall attest that the information specified in the application form is accurate and will be regularly updated
3. The same website is used to update information previously submitted for registration purposes, e.g. a change in the postal address. In this case the **local manufacturer** has 10 calendar days from the occurrence of the change to provide the SFDA/MDS with revised information.

4. The SFDA/MDS may ask the **local manufacturer** to confirm the registration information it holds remains true and complete.

## B. Licensing Requirements

*Exert from CHAPTER FIVE of the **MEDICAL DEVICES INTERIM REGULATION***

### Article Fifteen

- A. **Local manufacturers involved in distribution activities**, as well as importers, distributors, and authorized representatives involved in importation or distribution activities, shall apply for an establishment license.

### COMMENTS

1. Where a **local manufacturer** is involved in the distribution of medical devices within the KSA, be those of either its own or another organizations manufacture, it is subject to additional requirements and responsibilities. Implementing Rule MDS-IR4 *Establishment Licensing* should be referred to by **local manufacturers** involved with this activity together with separate guidance for distributors, available on the SFDA website.
2. The Interim Regulation requires a **local manufacturer** to be licensed with the SFDA only if it distributes medical devices within the KSA.

## PART II

### Applying for Medical Device Marketing Authorization

#### C. General Provisions and Application Procedure

*Exert from CHAPTERS ONE & TWO of the **MEDICAL DEVICES 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.

##### **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 authorisation.

##### **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 authorisation, 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 labelling and conditions of supply and/or use.

### **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 authorisation 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.

### **COMMENTS**

1. From 14<sup>th</sup> February 2011 medical devices that have SFDA marketing authorization may be placed on the market within the KSA.
2. After 14<sup>th</sup> August 2011 only medical devices that have SFDA marketing authorization may be placed on the market within the KSA.
3. Marketing authorization is required for
  - all medical devices whatever their risk class;
  - contact lenses for cosmetic as well as for medical purposes; and
  - laser surgical equipment intended for cosmetic as well as medical purposes.

It is not required for medical devices designed and constructed by health facility staff for internal use within that health facility, alone.

4. While an accessory to a medical device is not of itself a medical device, the Interim Regulation applies equally to it (see Article Five above), and its **manufacturer** must obtain authorization to market it within the KSA.
5. A **local manufacturer** who transforms or modifies a medical device on his own behalf (i.e. without the permission and oversight of its original manufacturer), 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.
6. Before a **local manufacturer** may apply for KSA market authorization for one of the medical devices it manufactures, it must
  - register with the MDNR (see Part I Section A, above);
  - comply with the regulatory requirements that would permit it to place the device on the market of one of the GHTF Founding Member jurisdictions (namely, Australia, Canada, Japan, the USA or the EU); and
  - comply also with provisions specific to the KSA concerning, for example, labelling, storage/installation and advertising. The **local manufacturer** may choose which of these jurisdictions it uses as the basis of its subsequent SFDA marketing authorization application (MDMA).
7. Information is submitted to the SFDA using the electronic application forms found on the Medical Device Marketing Authorization (MDMA) portion of its website. After indicating which of the five GHTF Founding Member jurisdictions will be used as the basis of the MDMA application, the **local manufacturer** will be directed to the appropriate part of the website. Implementing Rule MDS-IR6 *Marketing Authorization* and the associated document, MDS – G5 *Guidance on Marketing*

*Authorization Procedures*, describes the application procedure and the documentary evidence that has to be provided to support the claims made in paragraph 6 above. Both documents may be downloaded from the SFDA website.

Evidence from only one GHTF Founding Member jurisdictions, is required, even where the device is marketed in more than one.

8. Two categories of information must be provided. The first requires general information (such as the **local manufacturer's** contact details) and information specific to the KSA. The second requires information specific to the particular GHTF Founding Member jurisdiction the **local manufacturer** has chosen as the basis of its MDMA application. In addition, the **local manufacturer** will hold, and make available to the SFDA upon request, additional documentary evidence to support its MDMA application.
9. Electronic copies of any advertising or marketing material that the **local manufacturer** intends to use in the KSA after the medical device has been authorized to be placed on the market are submitted to the SFDA through the MDMA. Marketing material includes, for example, product brochures, information on clinical performance, and publications from technical magazines. Advertising material includes, for example, written material; information available on the internet television or radio; and information available in electronic form. Advertising and marketing material may be prepared for professional persons, lay persons or both.
10. Where the MDMA application covers more than one medical device type (referred to as 'bundling' in some jurisdictions), the applicant shall provide a description of the various device types.
11. When the SFDA is satisfied the medical device meets the provisions of the Medical Devices Interim Regulation, it authorizes the **local manufacturer** to place the device on the KSA market by issuing a numbered Marketing Authorization Certificate, and assigning each device to which the certificate applies with a Medical Device Listing National Registry Number.

## PART III

### Activities after the Device Receives Marketing Authorization

#### D. Medical Device Listing Requirements

*Exerts from CHAPTER FOUR of the MEDICAL DEVICES INTERIM REGULATION*

##### Article Ten

**Manufacturers established within the KSA**, authorized representatives, importers and distributors of medical devices shall:

- B.** List medical devices with the SFDA.

##### Article Thirteen

**A.** The registrant [i.e. the **local manufacturer**] shall before it is involved in the supply of any medical device to the market for the first time:

2. Provide the required medical device listing information to the MDNR.

- B.** Attest to their accuracy.

**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

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

*Exert from Implementing Rule MDS-IR3 Medical Device Listing*

**Article Six:** Parties subject to listing requirements

- A. Establishments involved in importation or distribution activities are subject to listing requirements. Where a retail pharmacy distributes medical devices, it shall be subject to listing requirements for this activity alone.

**Article Seven:** Timing of listing

The registrant [i.e. the **local manufacturer**] shall submit listing information for SFDA marketing authorized medical devices when these devices are supplied to the KSA market.

**Article Eight:** Information to be submitted for listing purposes

For the purposes of medical device listing, the registrant shall access the electronic application form available in Section C of the MDNR by providing the Medical Device National Listing Number of the medical device it is supplying to the KSA market. It shall complete the electronic form submitting the following information:

- A. Indicate the quantity, serial numbers or lot numbers, shipment date, and destination of the medical devices that are being supplied to the KSA market.
- B. An indication that the information provided is either a new entry or an update of previously submitted information.
- C. The date when the listing information is submitted.

**COMMENTS**

1. When the **local manufacturer** has obtained SFDA marketing authorization for a medical device it manufactures and is responsible also for distributing the device within the KSA,

it is required to provide additional listing information to the Medical Device National Registry (MDNR) whenever it places an authorized medical device on the KSA market. Implementing Rule MDS-IR3 **Medical Device Listing** (see exert above) describes the procedure and MDS – G1 Guidance for **Medical Device Importers** and Distributors describes the responsibilities of organisations involved in the activity of distributing medical devices.

2. The additional device listing information is provided through the electronic form located in Section C of the MDNR before an authorized medical device is shipped to a customer or intermediary. It is opened by first entering the MDMA Certificate Number which results in the **local manufacturer** being presented with a list of the devices to which the certificate applies (see Part II Section C 10). The **local manufacturer** shall indicate the device type it is placing on the KSA market and provide the following information:
  - the shipment date;
  - the quantity with serial numbers (or lot numbers) of the shipment;
  - the destination of the medical devices that are to be supplied.
3. The same website is used also to update previously submitted information, e.g. a change in the contact information. In this case the **local manufacturer** has 10 calendar days from the occurrence of the change to provide the SFDA with revised information.
4. The SFDA may ask the **local manufacturer** to confirm the listing information it holds remains true and complete.

## E. Storage, Handling and Transport of Medical Devices

**Local manufacturer** shall ensure the medical devices it manufactures are properly packed, handled and stored, as well as transported in a

suitably vehicle, taking into account the environmental conditions to be encountered within the KSA with respect to temperature, humidity, vibrations and the risk of physical damage. It shall also:

- provide written information, both in the Arabic and English language, to organizations responsible for transporting its devices, to distributors and to users, on the required transportation, handling and storage conditions while each is responsible for the device; and
- ensure the packaging of a consignment of medical devices is clearly identified and that an individual medical device within the consignment is accompanied by all relevant documentation, such as, the instructions for installation, maintenance and use, in the language required by the Interim Regulation.

## F. Post-Market Surveillance of Medical Devices

*Exerts from CHAPTER EIGHT of the **MEDICAL DEVICES INTERIM REGULATION***

### Article Thirty

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 One

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

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### Article Thirty Three

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

### Article Thirty Four

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.

## COMMENTS

1. CHAPTER EIGHT of the Medical Device Interim Regulation requires the SFDA to take all appropriate measures to ensure that medical devices authorized to be placed on the KSA market are subject to post-marketing surveillance (see exert from the Interim Regulation, above). It comprises two activities, namely medical device adverse event management, of which a medical device vigilance system is an integral part, and market control. Together these help to ensure and maintain a high level of patient health and safety with respect to medical devices.
2. Implementing Rule MDS-IR7 *Post-Marketing Surveillance* and the associated guidance published on the SFDA website describe the **local manufacturer's** responsibilities in respect of this procedure. These include requirements to:
  - Report to the SFDA's National Centre for Medical Devices Reporting (NCMDR), any Field Safety Corrective Action that may affect medical devices supplied to the KSA; and
  - Investigate any adverse event of which it becomes aware. If the **local manufacturer** confirms a malfunction or deterioration in the characteristics and/or performance of the medical device, as well as any inadequacy in the labelling or the instructions for use, has led, or might have

- led, to the death of a patient, user or third person, or to a serious deterioration in the state of health of a patient, user or third person, it shall submit an adverse event report to the SFDA and agree a corrective action plan.
3. An important aspect of effective post-market surveillance is the need of the SFDA, health authority and/or **local manufacturer** to identify an individual medical device so that it may be traced, examined, or recalled after it has been put into service. Therefore, the **local manufacturer** is required to label the medical devices it manufactures with an unambiguous identification, such as a batch code / lot number, or serial number, preceded by the word LOT or SERIAL NUMBER (or an equivalent symbol) as appropriate. In general, consumable and single-use devices have a batch code while powered medical devices have individual serial numbers.

## G. Post-Marketing Responsibility for Advertising and Marketing Material

*Exerts from CHAPTER FOUR of the **MEDICAL DEVICES INTERIM REGULATION***

### **Article Thirty Nine:** Advertising

- A. The advertising of a medical device for which the SFDA has not issued a marketing authorisation 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.

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*Exerts from Implementing Rule MDS-IR 6 Marketing Authorization*

**Article Eight:** Documentary evidence that the medical device complies with the National Provisions of the KSA

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

- B. A copy, in electronic form, of the advertising and marketing materials that will be used in the KSA if any.

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

- F. Advertising and marketing information shall be in English and, where justified, in Arabic.

## COMMENTS

1. The local manufacturer is responsible for ensuring all advertising and marketing materials (either that submitted with the MDMA, newly prepared material or revised versions of the material submitted through the MDMA) are approved by the SFDA before they are used.
2. Once the medical device has been approved by the SFDA for marketing in the KSA, the **local manufacturer** shall write to the SFDA asking for the previously provided advertising and

marketing material, if any, to be approved. The letter shall include the Medical Device National Listing Number of the relevant medical device, the proposed target recipient (e.g. nurse, paediatrician, oncologist, radiographer, biomedical engineer, lay person) and intended placement of any advertisement (e.g. newspaper, professional magazine, television, radio, internet, exhibition material, and the like).

3. Any newly prepared or revised advertising or marketing material is submitted manually to the SFDA with a covering letter that includes the Medical Device National Listing Number of the relevant medical device, the proposed target recipient (e.g. nurse, paediatrician, oncologist, radiographer, biomedical engineer, lay person) and intended placement of any advertisement (e.g. newspaper, professional magazine, television, radio, internet, exhibition material, and the like).
4. The SFDA shall review the submitted advertisements and marketing materials to confirm any performance or safety claims are consistent with the information provided with the original MDMA.
5. The SFDA may ask the applicant to provide additional information and documentation before it reaches a decision.
6. Once satisfied, the SFDA will approve the submitted material in writing and it is only then the **local manufacturer** may use it.
7. If the **local manufacturer** supplies its medical devices to the KSA through an independent distributor, it must copy all approved advertising and marketing materials to the distributor and indicate the proposed recipient (e.g. nurse, paediatrician, oncologist, radiographer, biomedical engineer, lay person) and placement (e.g. newspaper, professional magazine, television, radio, internet) of any advertisement.