

**MDS - G5**

**GUIDANCE ON**

**MARKETING AUTHORIZATION PROCEDURES**

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## A. General Provisions

*Exerts from CHAPTERS ONE and 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 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 authorization.

### **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.

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*Exerts from Implementing Rule MDS-IR 5 Licensing of Authorized Representatives*

**Article Five : General**

- D. Where a manufacturer intends to make available more than one category or generic device group of medical device to the KSA market, it may designate a different authorized representative for each device category or generic device group.

**COMMENTS**

1. From 14<sup>th</sup> February 2011 medical devices that have a 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 a SFDA marketing authorization may be placed on the market within the KSA.
3. Marketing authorization is required for
  - all medical devices whatever their classification;
  - 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. Medical device marketing authorization (MDMA) applications shall be made by either a local manufacturer or, where the manufacturer is established outside the KSA, by its authorized representative.
5. Before applying for marketing authorization, the local

manufacturer must be registered by the SFDA, and the authorized representative both registered and licensed. Information on these procedures is available on the SFDA website in documents entitled MDS - G2 ***Guidance for Local Manufacturers*** and MDS – G3 ***Guidance for Authorized Representatives***.

6. An overseas manufacturer may wish to market a wide range of medical devices within the KSA. These devices may have very different purposes (e.g. orthopaedic implants, diagnostic monitors, and surgical instruments). It is the manufacturer's choice whether it appoints one authorized representative to act on its behalf for the whole range or different ones for each device category.
7. While an accessory to a medical device is not of itself a medical device, the Interim Regulation applies equally to it (see Article Five of the Interim Regulation above), and requires authorization from the SFDA to be placed on the KSA market.

## **B. Application Procedures**

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

### **Article Eleven**

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

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

### **Article Eighteen**

- A. The manufacturer or its authorized representative shall for the medical devices it wishes to place on the market of the KSA:

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.

## COMMENTS

1. Information is submitted to the SFDA using the electronic application forms found on the 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 applicant (either a local manufacturer or, where the manufacturer is established outside the KSA, by its authorized representative) will be directed to the appropriate part of the website. Implementing Rule MDS-IR6 **Marketing Authorization** describes the application procedure and the documentary evidence that has to be provided to support the applicant's claim that the device meets all relevant requirements of the Medical Device Interim Regulation.

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

2. Two categories of information must be provided. The first requires general information (such as the applicant's contact details) and information specific to the KSA. The second requires information specific to the particular GHTF Founding Member jurisdiction the manufacturer has chosen as the basis of the MDMA application. In addition, the manufacturer will hold, and make available to the SFDA upon request, additional documentary evidence to support its MDMA application (see Section I below).
3. The documentation provided shall relate to the medical device that is the subject of the MDMA and be sufficient to:
  - identify the medical device that is the subject of the application, its manufacturer and the legal entity making the application (see Section E below);
  - demonstrate the device complies with all relevant provisions specific to the KSA (see Section F below); and
  - demonstrate the manufacturer of the device has been authorized to place the device on the market in one of the five GHTF Founding Member jurisdictions (see Section G below).
4. The language requirements for the documents accompanying the MDMA are specified in Section H below.
5. The applicant's attestation, downloaded onto the MDMA, shall be in the format attached to this document as ANNEX ONE.
6. When the SFDA is satisfied the medical device meets the provisions of the Medical Devices Interim Regulation, it authorizes the 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 (see Section I below).

7. The applicant shall provide a statement to confirm it shall report to the SFDA's National Centre of Medical Devices Reporting (NCMDR), any Field Safety Corrective Action that may affect safety and/or the performances of medical devices placed on the market or put into service in the KSA. Further requirements on adverse events management and reporting is provided in both Implementing Rule MDS-IR7 *Post-Marketing Surveillance* and MDS – G6 *Guidance on Post-Marketing Surveillance*.

### C. MDMAs Incorporating More Than One Medical Device Type

1. Where the applicant's MDMA groups more than one medical device type (referred to as 'bundling' in some jurisdictions) within a single application procedure, the grouped medical device types shall all have been authorized for marketing within the GHTF Founding Member jurisdiction, upon which the MDMA is based, on the same basis.
2. Where the MDMA procedure involves medical device types having different purposes, technical performance and classification, the applicant will have to access the MDMA portion of the SFDA's website on multiple occasions to provide the required information. While some of that information will be common, the KSA national provisions will vary with the different medical device types,
3. The SFDA reserves the right to accept or reject bundled MDMA applications.

## **D. Information to be Provided to the SFDA to Identify the Device, its Manufacturer and the Applicant**

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

### **Article Five: General requirements**

- A. The manufacturer shall either directly, or where the manufacturer is established overseas, through his authorized representative, access the electronic application form available on the MDMA portion of the SFDA website and provide the SFDA with documentary evidence, as specified in Articles Six, Seven and Eight.
- B. The SFDA shall adopt and publish a guideline to ensure a coherent and uniform application of Articles Six to Ten.

### **Article Six: General information**

- A. Contact details of the manufacturer.
- B. Where the manufacturer is established within the KSA, his establishment National Registry number.
- C. Where the applicant is an authorized representative of a manufacturer established outside the KSA, his contact details and establishment National Registry Number.
- D. The name and contact details of the person responsible for completing the application form.
- E. Information on the medical device the manufacturer wishes to supply to the market.
- F. An indication of whether or not the device that is the subject of the application complies with the relevant medical device regulations of one or more of the GHTF Founding Member jurisdictions (namely Australia, Canada, Japan, USA, or the EU).

## COMMENTS

1. Where the applicant is a local manufacturer, he shall provide his company name and contact information, together with the contact details of the person responsible for the medical device MDMA application. Also, he shall provide his Establishment National Registry Number
2. Where the applicant is an authorized representative, he shall provide the same information as in the previous paragraph, together with the contact information of the overseas manufacturer on whose behalf he is acting, and his Authorized Representative License Number.
3. The applicant shall provide information that will allow the medical device that is the subject of the application to be identified unambiguously. Where the MDMA application procedure covers more than one medical device type, the requirements in Sections C above must be met. If they are not, the MDMA application will be rejected and the applicant must resubmit multiple applications.
4. Furthermore, the application shall indicate the format of the identifier number that will appear on each medical device for the purpose of:
  - allowing the device to be tracked as it progresses from manufacturer to user along the supply chain;
  - providing a link between an individual device and the KSA marketing authorization; and
  - operating efficient border and market control procedures.
5. The applicant shall indicate, for information purposes only, which of the GHTF Founding Member(s) allows the medical device that is the subject of the MDMA application, onto its market.

## **E. Information to be Provided to the SFDA on Specific Saudi Provisions**

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

### **Article Eighteen**

A) The manufacturer or its authorized representative shall for the medical devices it wishes to place on the market of the KSA:

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.

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

### **I I. Advertising**

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

- 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.

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

#### **Article Five: General requirements**

- A. The manufacturer shall either directly, or where the manufacturer is established overseas, through his authorized representative, access the electronic application form available on the MDMA portion of the SFDA website and provide the SFDA with documentary evidence, as specified in Articles Six, Seven and Eight.

#### **Article Six: General information**

- H. Documentary evidence that the medical device complies with the National Provisions of the KSA as described in Article Eight.

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

- B. A copy, in electronic form, of the labeling associated with the medical device that will be placed on the market of the KSA, i.e.

both the labels affixed to the device and the instructions for use, and show that the text of the different elements of the labeling and their content take appropriate account of the intended use of the devices and the qualifications of the users in the KSA.

- C. Where the device is connected to an a/c power supply, confirm it is designed to operate with a 60 Hertz supply at nominal values of either 220 or 380 volts and is fitted with the appropriate a/c power connector, and provides the required electrical safety conditions. Also, ensure that the device shall perform as intended when subject to the other environmental factors encountered in the KSA.
- D. A copy, in electronic form, of the manufacturer's instructions to ensure the medical devices intended to be placed on the KSA market will be correctly handled, transported, stored, installed, maintained and disposed of and to provide information that allows users and other persons, as appropriate, to be trained in their proper handling, storage, use and maintenance.
- E. A copy, in electronic form, of the advertising and marketing materials that will be used in the KSA, if any.
- F. An attestation that the medical device complies with the national provisions of the KSA's Medical Devices Interim Regulation.

## COMMENTS

1. As well as providing documentary evidence that the medical device that is the subject of the MDMA application complies with the medical devices regulation that applies to it within a selected GHTF Founding Member jurisdiction (see Section F below), the applicant must provide evidence that the device complies with requirements specific to the KSA. These concern labeling, any a/c power supply, environmental factors, handling/ transportation/ storage, and advertising.

## Labeling

2. The SFDA requires electronic copies of the labels affixed to the

device and its wrappers, as well as a copy of the instructions for use, in the format that will be used when the device is marketed within the KSA. The SFDA will confirm, in particular, they satisfy requirements in respect of product identification, language, and tracking of individual devices through the supply chain.

3. Where the device is intended for use by lay persons, the text of labeling shall be written in terms readily understood by such persons.

### **Medical devices connected to an a/c power supply**

4. Where the device is intended to be connected to an a/c power supply, the label and/or the instructions for use will indicate the nominal frequency and the voltage values with their tolerances for which the devices have been designed. The SFDA shall ensure the indicated values are suitable for conditions in the KSA.
5. The applicant is required to provide a statement confirming that the devices will maintain the required electrical safety conditions and perform to specification within the indicated electrical conditions.

### **Environmental factors**

6. The instructions for use shall provide information on any measures taken to accommodate the specific non electrical environmental and/or conditions of use encountered in the KSA , such as (a) local operating temperature and humidity conditions and (b) the level of protection of the devices against electro-magnetic disturbances, when applicable.
7. The applicant is required to provide a statement confirming that the devices will maintain its specified performance when subject to the environmental factors that may be encountered within the KSA.

### **Handling, transportation and storage**

8. The manufacturer shall specify the conditions importers and/or distributors have to implement in order to ensure proper storage,

handling and transportation of the medical devices supplied to the KSA market. Further information is provided in MDS – G1 *Guidance for Medical Device Importers and Distributors*, available on the SFDA website.

## Advertising

9. Where the manufacturer has already prepared advertising and marketing material, intended to be used in the KSA, at the time of application, a copy shall be provided to the SFDA.
10. As part of the requirements specific to the SFDA, electronic copies of any advertising or marketing material that the 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.
11. Marketing material includes, for example, product brochures, information on clinical performance, and publications from technical magazines.
12. Advertising material includes, for example, written material, information available on the internet television or radio, exhibition material and the like, and information available in electronic form.
13. Advertising and marketing material may be prepared for professional persons, lay persons or both.

## **F. Information to be Provided to the SFDA on the Regulatory Status of the Device in the GHTF Founding Member Jurisdiction**

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

### **Article Eighteen**

- 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.

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

### **Article Five: General requirements**

- A. The manufacturer shall either directly, or where the manufacturer is established overseas, through his authorized representative, access the electronic application form available on the MDMA portion of the SFDA website and provide the SFDA with documentary evidence, as specified in Articles Six, Seven and Eight.

### **Article Six: General information**

- G. Documentary evidence that the medical device complies with the regulations of a particular GHTF Founding Member jurisdiction as described in Article Seven.

### **Article Seven: Documentary evidence that the medical device complies with the regulations of a particular GHTF Founding Member jurisdiction**

The applicant shall specify which of the GHTF Founding Member jurisdictions is the basis of its application for marketing authorization within the KSA and provide the SFDA with information and documentary evidence, as follows:

- A. The classification of the medical device, or in-vitro medical device, according to the regulations that apply.
- B. Evidence that the medical device complies with the conformity assessment requirements that apply to it in the jurisdiction, including any registration or listing requirements.
- C. Evidence, where such is required, that the manufacturer's quality management system is in place, covers the appropriate processes and is subject to independent audit. Where the manufacturer has decided voluntarily to implement a quality system, evidence shall be provided of its proper application.
- D. Where the manufacturer's claim that its device complies with the medical device regulations is not subject to premarket review by the Regulatory Authority (RA), or a Conformity Assessment Body appointed by the RA to act on its behalf, an indication of the location of the technical information that supports the manufacturer's claim. The SFDA may, when duly justified, require the manufacturer to provide a summary of these documents.
- E. An attestation that the medical device complies with the provisions of the medical device regulations that apply within the GHTF Founding Member jurisdiction that has been selected as the basis of the application.

## COMMENTS

1. As well as providing documentary evidence that the medical device that is the subject of the MDMA application complies with requirements specific to the KSA (see Section F above), the applicant must provide evidence that the device complies with the medical devices regulation that applies to it within the particular GHTF Founding Member jurisdiction that has been chosen as the basis of the application. By indicating which GHTF jurisdiction is being used, the applicant will be directed to the relevant part of the website.
2. First, the applicant shall indicate whether the GHTF Founding Member marketing authorization is for a single device type or is for multiple device types, and provide information to allow the authorized device(s) to be identified (see Section C above).
3. Then, the applicant shall provide documentary evidence that the device that is the subject of the MDMA application complies with the medical devices regulation that applies to it within the selected GHTF Founding Member jurisdiction and indicate the conformity assessment technique that has been applied to it. Such evidence may consist of, for example:
  - a medical device listing number published by the regulator concerned; or
  - a letter from the regulator that raises no objection to the device being placed on the market; or
  - a certificate or report issued by the regulator (or its designated assessment organization) confirming the device has been subject to the appropriate conformity assessment review and is found to be in compliance.
4. The applicant shall specify whether the medical device is manufactured within an established quality management system (QMS) and indicate whether this is a mandatory requirement for the applicable conformity assessment procedure or applied on a voluntary basis.

5. The applicant will specify:
  - the activities included within the QMS,
  - a copy of the current QMS approvals/certificate held by the manufacturer that relate to the device that is the subject of the SFDA MDMA application, and
  - the name of the organization undertaking the QMS audit.
6. Within each jurisdiction there are medical devices that are exempted from premarket assessment by either the regulator or its designated assessment organization. Such devices are generally acknowledged as presenting fewer hazards to patients and users than others. The regulatory approach with such devices is to rely in the first place on the manufacturer's assessment that the device is safe and performs as intended; and use post-market controls to monitor their behaviour when put into service. For example:
  - in Australia and the EU such devices have to comply with the same Essential Requirements for Safety and Performance as do devices with a higher classification;
  - in the USA such devices are subject to 'General Controls';
  - in Canada the applicant must provide evidence the device is distributed within the GHTF Founding Member jurisdiction. Such evidence may be a sales catalogue, sales invoice or published medical device listing number.
7. The applicant's attestation that the device(s) that is the subject of the application complies with the medical devices regulations that apply within the GHTF Founding Member jurisdiction shall be in the form shown in ANNEX ONE.
8. The applicant shall provide the address of the location from which the technical documentation that supports this attestation may be obtained.

## G. Language Requirements

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

### **Article Eighteen**

- A. The manufacturer or its authorized representative shall for the medical devices it wishes to place on the market of the KSA:
  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.

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

### **Article Five: General requirements**

- A. The manufacturer shall either directly, or where the manufacturer is established overseas, through his authorized representative, access the electronic application form available on the MDMA portion of the SFDA website and provide the SFDA with documentary evidence, as specified in Articles Six, Seven and Eight.

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

- A. Documents to be provided to the SFDA that relate to the original marketing authorization in the GHTF Founding Member jurisdiction shall be in English, unless the SFDA has given prior agreement that

another language is acceptable. However, where the language used is other than English, a summary and/or translation of the relevant parts of the document shall be provided in English.

- B. The manufacturer shall indicate to the SFDA the location of the technical documents that support its Declaration of Conformity that the medical device complies with the provisions of the medical device regulations of a GHTF Founder Member jurisdiction. When duly justified, the SFDA may request the applicant to provide parts of this technical documentation. Where the language used in such documentation is other than English, the applicant shall indicate this fact to the SFDA and may be requested to provide an English translation of the relevant parts of such documents.
- C. Labeling in the English language is acceptable where the user(s) of the medical device is likely to be professionally qualified. If the device is for use by a lay person, labeling shall be in both the Arabic and English languages.
- D. The following documents shall be in English:
1. Measures related to the application of the specific Saudi requirements.
  2. The declarations attesting that the medical devices comply with the regulation of the selected GHTF Founding Member jurisdiction and with the relevant specific Saudi provisions
  3. The undertaking to transmit to the SFDA all reportable adverse events.
  4. The mandate nominating the authorized representative, if any.
  5. Instructions on training of users or other persons.
- E. Instructions for the handling, storage, transportation, installation, maintenance and, disposal of the medical devices shall be in English and, where justified, in Arabic.

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

## COMMENTS

1. Documents to be provided to the SFDA by the applicant are expected to be in English, unless, on a duly justified request, SFDA agrees that some of these documents may be in another language accompanied by a translation into English of the relevant parts.
2. Documents held by the manufacturer could be in a language other than English. If the SFDA requires specific document of this type to be submitted to it for evaluation, it reserves the right to ask that they be accompanied by an English translation.
3. Where the device is intended to be used by lay persons, the labeling shall be in both the Arabic and English languages. Medical personnel in healthcare facilities are not considered to be lay persons.

## H. The Marketing Authorization Decision

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

### **Article Eighteen**

- 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 Nineteen**

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

## **Article Twenty**

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 One**

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

## *Exert from Implementing Rule MDS-IR 6 Marketing Authorization*

### **Article Five: General requirements**

- A. The manufacturer shall either directly, or where the manufacturer is established overseas, through his authorized representative, access the electronic application form available on the MDMA portion of the SFDA website and provide the SFDA with documentary evidence, as specified in Articles Six, Seven and Eight.

### **Article Ten: The evaluation of the application and validation of documents**

- A. The evaluation process will verify if all the appropriate information is provided.
- B. When the required information and documentation has been provided to the MDMA, the SFDA shall allocate each application with its associated documents to a CAB (Conformity Assessment Body), duly appointed to assist the SFDA, and ask it to verify that the medical device complies with the provisions specified in this Medical Devices Interim Regulation. It is not intended that the CAB repeats the

work undertaken by the Regulatory Authority or certification bodies of the GHTF Founding Member jurisdiction. However, it will inspect the documents and information provided to it and confirm to its own satisfaction that such documentation is sufficient and applies to the medical device under review.

- C. The CAB determines the adequacy of the documentary evidence in support of the applicant's attestation of conformity with the:
  - 1. Specified regulations of a GHTF Founder Member jurisdiction, and
  - 2. National provisions of the Medical Devices Interim Regulation.
- D. Where the evidence offered is inadequate, the CAB will ask the SFDA to request the applicant to provide additional technical documentation but, where it does so, must justify such a request. The SFDA may also verify directly with the organizations that have issued any certificates provided by the applicant that they have not expired and/or the conditions of their validity.
- E. The CAB may request the SFDA to interrogate the NCMDR database for any reported incidents that involve the medical device that is the subject of the market authorization application.
- F. When the CAB has reached a conclusion as to whether or not the manufacturer has met the requirements of the Medical Devices Interim Regulation it shall recommend to the SFDA that it may issue the marketing authorization.

**Article Eleven: Marketing authorization Once satisfied with the information received, the SFDA issues:**

- 1. A written marketing authorization, in both Arabic and English, to the manufacturer that permits the relevant medical devices to be placed on the market of the KSA. It shall indicate the dates of both its issue and expiry, having taken account, among other factors, of the conditions of validity of the authorization in the GHTF Founding Member jurisdiction, if any.

2. A Marketing Authorization Number.
3. Medical Device National Listing Numbers for the medical devices included in the marketing authorization.

## COMMENTS

1. The SFDA shall, with the assistance of a designated Conformity Assessment Body (CAB) working on its behalf, assess the information and documents provided to it by the applicant to ensure they align with the claims the applicant makes in its attestation (see ANNEX ONE).
2. Where either the CAB is unable to make a recommendation, or the SFDA is unable to reach a marketing authorization decision, using the information and documents provided to it by the applicant, the SFDA will explain to the applicant why it requires additional technical documentation. Such documentation may consist of, for example:
  - the full quality system documentation for a specific device family and the amendments of the approved quality system;
  - the most recent QMS audit report undertaken by an independent body;
  - the technical annexes attached to the EC-type examination certificate (EU only);
  - the 510(k) notification (USA only);
  - technical documentation to demonstrate the device meets regulatory requirements for safety and performance;
  - an independent test report confirming compliance with international standards for electrical safety and electromagnetic compatibility; or
  - a summary of clinical evidence.



3. When the SFDA and its designated CAB are satisfied with the information and documents provided to it and with the manufacturer's commitments, the SFDA shall authorize the local manufacturer or the overseas legal manufacturer in writing, as applicable to place the device on the KSA market, and assign a Medical Device Listing National Registry Number to the device on whose behalf the authorization has been requested by its authorized representative. The written authorization shall indicate:
  - the details of the manufacturer,
  - sufficient information to identify the medical devices or the device group, and
  - the period of its validity.

The written medical device marketing authorization remains the property of the legal manufacturer, whether local or overseas, and not of an authorized representative or importer.

4. The end date of the period of validity of the written medical device marketing authorization will be the same as that of the marketing authorization granted in the GHTF Founding Member jurisdiction unless the GHTF Founding Member's authorization is open ended and does not indicate a validity end-date, or where the device has been marketed through a self-declaration process (e.g. Class I devices that are not sterile or having a measuring function under EU regulations), where validity shall be 3 years.
5. If the documentary evidence provided to the SFDA with the original MDMA application changes before the written medical device marketing authorization has expired, the local manufacturer or authorized representative, as applicable, shall write to the SFDA informing them of this fact. Subsequently, the SFDA shall require the updated information to be provided using the electronic form found on the MDMA portion of SFDA's website. The SFDA shall review the submitted information and decide whether or not it needs to modify the device's marketing authorization.

6. Sixty days before the written medical device marketing authorization expires, the local manufacturer or authorized representative, as applicable, shall apply for its extension using the electronic form found on the MDMA portion of SFDA's website. The SFDA shall review the submitted information when received and, if the documentary evidence remains unchanged, renew the written marketing authorization. If the documentary evidence differs from that provided with the original MDMA application, the SFDA shall review the changes before reaching its marketing authorization decision.





## ANNEX ONE

### Attestation accompanying Application for Marketing Authorization \*

*[To be printed on Manufacturer Letterhead]*

Name and Address of Manufacturer:

.....  
.....  
.....

I hereby declare that the medical device(s) listed below complies with:-

1. The provisions of the medical device regulations that apply within the GHTF Founding Member jurisdiction that has been selected as the basis of the application.
2. The specific KSA national provisions within the MEDICAL DEVICES INTERIM REGULATION.

*GHTF Founding Member jurisdiction that has been selected as the basis of the application, selected from:*

*AUSTRALIA / CANADA / EU / JAPAN / USA.*

List of devices :

1. *(Trade Brand name)*
2. *(Trade Brand name)*
3. ....

Authorized Signatory:

*Name:*

*Job Title:*

*Signature:*

*Date:*

*\*This is for reference only. Valid version is incorporated into MDMA system.*