

MDS - G3

GUIDANCE FOR MEDICAL DEVICE AUTHORIZED REPRESENTATIVES

Part I: Pre-License Activities	3
Part II: Post-License Activities of Authorized Representatives	13
ANNEX I:	24
Sample agreement between a single legal manufacturer and an authorized representative	
ANNEX II:	31
Sample agreement between an organization representing multiple legal manufacturers within a single company and an authorized representative	



PART I

Pre-License Activities

A. Designation of Authorized Representatives

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

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.

~

Exerts from Implementing Rule MDS-IR5 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. Every manufacturer established outside the KSA (i.e. an overseas manufacturer) is required to appoint an **authorized representative**, resident within the KSA, to act on its behalf. The SFDA will contact the overseas manufacturer through the **authorized representative** with regard to the manufacturer's

obligations under the Medical Devices Interim Regulation. Where a manufacturer intends to place medical devices onto the KSA market that fall within more than one device category or generic device group¹, it may either designate a single **authorized representative** for all the devices it intends to market, or designate a different **authorized representative** for each device category or generic device group.

2. The manufacturer and **authorized representative** are signatories to a contract, or mandate, describing their respective responsibilities. A primary responsibility of the **authorized representative** is to apply, on behalf of the manufacturer, for a SFDA medical device marketing authorization. Such an application is based on that manufacturer having an existing marketing authorization for the medical device that is the subject of the application in a GHTF Founding Member jurisdiction.
3. An **authorized representative** may represent more than one manufacturer provided it has the necessary mandates and licenses.
4. An overseas manufacturer of contact lenses and laser surgical equipment that are intended to be used only for cosmetic rather than medical purposes is subject to the provisions of the Interim Regulation and, if located outside the KSA, will require an **authorized representative** to act on its behalf.
5. The minimum content of the mandate between the manufacturer and the **authorized representative** is specified in Article Six of Implementing Rule MDS-IR 5 Licensing of **authorized representative**
6. Where an organization, acting as an **authorized representative** has also a legal entity involved in importation or distribution activities of medical devices within the KSA, it is subject to the additional requirements and responsibilities of such a body. MDS – G1 **Guidance for Medical Device Importers and Distributors** describes the requirements.

¹ **Generic device group:** means a set of devices having the same or similar intended uses or commonality of technology allowing them to be classified in a generic manner not reflecting specific characteristics.

B. Applying for Establishment Registration

*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:

- A. Register their establishments with the SFDA.

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.

~

Exerts from Implementing Rule MDS-IR 2 Establishment Registration

Article Eight:

For the purpose 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 **authorized 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.
- C. Where the registrant is an **authorized representative**, it shall also provide 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 place of business of the manufacturer(s) on whose behalf it is acting, together with the name and position held of the person responsible within the manufacturer's organization.
- 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 [i.e. the **authorized representative**] is required to :

- B. Attest to its accuracy [i.e. of the registration information].
- 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 **authorized representative** is required to apply to the SFDA for registration purposes through the Medical Devices National Registry (MDNR) website, by choosing the appropriate activity i.e. AR, and be issued with an establishment National Registry Number. Implementing Rule MDS-IR2 *Establishment Registration* (see exerts above) describes the information to be provided.
2. Having provided the necessary contact information for itself and the manufacturer, the **authorized representative** shall attest that such information is accurate and will be regularly updated.
3. The MDNR is used to update previously submitted information also, e.g. a change in the contact information or appointment as an **authorized representative** for an additional manufacturer. In this case the **authorized representative** has 10 calendar days from the occurrence of the change to provide the SFDA/MDS with revised information.
4. The SFDA may ask the **authorized representative** to confirm the registration information it holds remains true and complete.

C. Applying for a License

Exerts from Implementing Rule MDS-IR5 Licensing of Authorized Representatives

Article Five: General

- A. Establishment licensing is intended to ensure that an **authorized representative**.
 1. Has been properly appointed to represent a particular manufacturer in the KSA;
 2. Possesses a written mandate describing the activities for which it acts on the manufacturer's behalf and these are sufficient to ensure the proper application of the relevant provisions of the Medical Devices Interim Regulation; and
 3. Has set up appropriate procedures to comply with the mandated activities.
- B. Only an **authorized representative** holding a valid establishment license, issued by the SFDA, is permitted to legally act on behalf of the manufacturer in relation to the relevant provisions of the Medical Device Interim Regulation and the corresponding Implementing Rules. Each authorized representative shall be in possession of an Establishment Registry Number before it applies for a license.
- C. The **authorized representative** shall have separate licenses for each manufacturer it represents within the KSA.
- D. Where a manufacturer intends to make available more than one category or generic device group of medical device to the KSA, it may designate a different **authorized representative** for each category or generic device group.

Article Six:

Activities to be performed by an **authorized representative**

- A. The mandate established between the manufacturer and the **authorized representative** shall be in writing, specify the mandated activities, and be subject to the laws of the KSA.
- B. The mandate shall, at a minimum, allow the **authorized representative** to:
 1. Represent the manufacturer in its dealings with the SFDA.
 2. List each medical device category or generic device group intended to be supplied to the KSA market.
 3. Access the electronic application form available on the MDMA portion of the SFDA website and provide the SFDA with all necessary supporting documentary evidence, required by CHAPTER II of Implementing Rule MDS – IR 6 *Marketing Authorization*.
 4. Cooperate with the SFDA on evaluations and actions taken during market surveillance and/or vigilance procedures described in Implementing Rule MDS - IR7 on *Post-marketing Surveillance*.
 5. Make the following information available to the SFDA when so required in relation to its marketing surveillance activities.
 - The marketing authorisation issued by the SFDA for the listed medical devices.
 - The documentation which was used to demonstrate compliance with the Regulation of the relevant GHTF founding member jurisdictions.
 - The documents approved by the SFDA demonstrating compliance with the specific Saudi provisions referred to

in Article 6 of Implementing Rule MDS – IR 6 *Marketing Authorisation*.

6. Inform the SFDA of any adverse events that have occurred outside the KSA but have consequences for medical devices that have been authorized to be placed on the market of the KSA. The **authorized representative** shall explain the circumstances and provide information on the corrective action the manufacturer has taken or intends to take.
 7. Inform the SFDA of all field safety corrective actions resulting from post-market follow-up investigations performed by the manufacturer for medical devices that have been authorized to be placed on the market of the KSA. The **authorized representative** shall explain the reason for the corrective action and provide information on the action the manufacturer has taken or intends to take.
 8. Cooperate with parties involved in distribution activities, installation and maintenance of medical devices that have been placed on the KSA market under its mandate.
- C. The manufacturer may, under his sole responsibility, authorise his representative to perform tasks other than those specified in paragraph B of this article.

Article Eight: Responsibilities of the SFDA

The SFDA shall for each manufacturer the **authorized representative** represents:

4. Issue the **authorized representative** with a license, valid for one year, when it is satisfied that the relevant requirements have been met.

COMMENTS

1. Each **authorized representative** requires a license, issued by the SFDA, before it undertakes its mandated activities. The licensing application is available on the Medical Device Establishment License (MDEL) part of the SFDA website.
2. The minimum content of the contract (i.e. the ‘mandate’) between the manufacturer and the **authorized representative** is specified in Article Six of Implementing Rule MDS-IR5 *Licensing of Authorized Representatives* (see exert above). Normally the legal manufacturer itself will be a signatory to the agreement (see Annex I for a sample contract) but there are situations when a single signatory will represent multiple legal manufacturers within the same organization (see Annex II for a sample contract). While not compulsory, following the format of the sample contract will simplify SFDA’s task of reviewing the licensing application.
3. The mandate indicates each medical device category² or generic device group the manufacturer expects to supply to the KSA Market.
4. The manufacturer may, under its sole responsibility, require the **authorized representative** to undertake tasks additional to those listed in Article Six B of Implementing Rule MDS-IR5 *Licensing of Authorized Representatives* (see exert above). Such tasks may be included in the mandate but are not assessed by the SFDA as it reaches its licensing decision.
5. The manufacturer may mandate a different **authorized representative** for each generic device group within a device category.

² **Selected from:** active implantable devices; anaesthetic and respiratory devices; dental devices; electro mechanical medical devices; hospital hardware; In Vitro Diagnostic medical devices; non-active implantable devices; ophthalmic and optical devices; reusable devices; single use devices; assistive products for persons with disability; diagnostic and therapeutic radiating devices; complementary therapy devices; biologically derived devices; healthcare facility products and adaptations; laboratory equipment.

6. In addition to a copy of the mandate, the **authorized representative** will have to provide copies of the procedures that support each of the activities specified in the manufacturer's mandate. In particular:
 - a procedure to inform the SFDA of any adverse events³ that have occurred outside the KSA but have consequences for medical devices that have been authorized to be placed on the market of the KSA;
 - a procedure to inform the SFDA of all field safety corrective actions⁴ instigated by the manufacturer for medical devices that have been authorized to be placed on the market of the KSA; and
 - agreement to cooperate with the SFDA/ when it undertakes its market surveillance and/or vigilance activities, as specified in Implementing Rule MDS-IR7 *Post-Marketing Surveillance*.
7. Once satisfied that the licensing application meets all relevant requirements, the SFDA shall issue the **authorized representative** with a license that is renewable annually. It is only after the license has been issued that the **authorized representative** may act on behalf of the overseas manufacturer in respect of the Interim Regulation and its associated Implementing Rules.
8. The same website is used to update previously submitted information, e.g. a change in the contact information. In this case the **authorized representative** has 10 calendar days from the occurrence of the change to provide the SFDA with revised information.

³ 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.

⁴ 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.

PART II

Post-License Activities of Authorized Representatives

D. Medical Device Marketing Authorization – 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 representative**, 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 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 labeling and conditions of supply and/or use.

COMMENTS

1. From 14th February 2010 medical devices that have a SFDA marketing authorisation may be placed on the KSA market. A mandatory element of obtaining SFDA marketing authorisation where the device manufacturer is established outside the KSA is an appropriate appointment of an **authorized representative**.
2. After 14th August 2011 only medical devices that have an SFDA marketing authorization may be placed on the market.
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 overseas manufacturer must obtain authorization to market it within the KSA.
5. Before an **authorized representative** may apply for KSA market authorization for one of the medical devices manufactured by an **overseas manufacturer**, it must
 - register with the MNDR (see Part I Section B, above);
 - be licensed by the SFDA (see Part I Section C, above); and the medical device must.
 - 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);

The **overseas manufacturer** may choose which of these jurisdictions it uses as the basis of its subsequent SFDA marketing authorization application (MDMA).

- comply also with provisions specific to the KSA concerning, for example, labeling, storage/installation and advertising.
6. 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 **authorized representative** 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 5, above. Both documents are available on the SFDA website.
 7. Two categories of information must be provided. The first requires general information (such as the **overseas manufacturer's** contact details) and information specific to the KSA. The second requires information specific to the particular GHTF Founding Member jurisdiction the overseas manufacturer has chosen as the basis of its MDMA application. In addition, the overseas manufacturer will hold, and make available to the SFDA upon request, through the **authorized representative**, additional documentary evidence to support its MDMA application.
 8. Electronic copies of any advertising or marketing material that the overseas 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.

9. 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.
10. When the SFDA is satisfied the medical device meets the provisions of the Medical Devices Interim Regulation, it authorizes the **overseas 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.

E. 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.

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 overseas manufacturer through its **authorized representative** 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 **authorized representative** 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 by the **authorized representative** 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 **authorized representative** 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 overseas manufacturer, its **authorized representative** or its distributor/s may use it.

7. The **authorized representative** must copy all approved advertising and marketing materials to the manufacturer's distributor(s) in the KSA (including any approved through the MDMA system), 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, exhibition material and the like) of any advertising.

F. Post-Marketing 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.

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.

~

*Exerts from Implementing Rule MDS-IR7 **Implementing Rule on Post-Marketing Surveillance***

Article Six: Medical device reportable adverse events occurring within the KSA

- A. The SFDA will encourage users and persons involved in the provision of healthcare within the KSA to inform the manufacturer, where appropriate, through its **authorized representative** and the SFDA, through its National Centre for Medical Device Reporting (NCMDR), of any adverse event that meets the following criterion:
- any malfunction or deterioration in the characteristics and/or performance of a medical device, as well as any inadequacy in the labeling or the instructions for use, which 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, use or third person.
- B. When the SFDA receives the information it shall ensure that the manufacturer of the device, or his **authorized representative**, is immediately and fully informed of the adverse event.

Article Seven: Medical device reportable adverse events occurring outside the KSA

- A. When an adverse event falling within the category described in Article Six paragraph A occurs outside the KSA and has potential consequences for a medical device that is placed on the KSA market, the manufacturer, through its **authorized representative**, shall

immediately inform the SFDA of the circumstances and provide all available details on the device concerned and the measures taken in cooperation with the authorising GHTF CA.

- B. Where the SFDA considers the adverse event is reportable and could have consequences for a medical device that is placed on the KSA market, it shall ensure the event is recorded at its National Centre for Medical Device Reporting and properly managed
- C. When the manufacturer, having investigated the adverse event, decides to instigate a field safety corrective action within the KSA, the manufacturer through its **authorized representative** shall inform the SFDA of this decision. Where justified, the SFDA shall issue a field safety notice to device users and/or hospital authorities, informing them of the manufacturer's corrective action plan and of the risks involved in continuing to use the device. The SFDA shall use its best endeavours to agree with the manufacturer the text of the field safety notice.

Article Eight: Medical device reportable adverse events occurring during post-marketing follow-up

When a reportable adverse event, which was identified during the manufacturer's post-marketing follow-up activities performed in the framework of its GHTF authorisation, leads to a field safety corrective action for a medical device that is authorized to be placed on the KSA market, the manufacturer shall inform the SFDA of the adverse event, through its authorized representative where appropriate, of the measures it intends to take and provide the SFDA with a copy of any relevant Field Safety Notice issued by the authorizing GHTF CA concerned.

~

Article Ten: Market control activities by the SFDA

- A. Where the SFDA has reason to suspect a medical device, authorized to be placed on the KSA market, does not, under normal conditions of use, meet the manufacturer's specification for safety and performance, it shall undertake appropriate checks by means of documentary verifications and, where justified, by physical inspection and/or testing of medical devices, placed on the market but not yet to be put into service, to assess the non-compliance and analyse the factor/s causing it. When non-compliance is proven, an examination is performed, where necessary, on an adequate sample of the medical devices to verify the systematic character of the non-conformity. Where relevant test reports or certificates, attesting conformity, issued by a NCA or, on a voluntary basis, a recognised Conformity Assessment Body, are made available to the SFDA, it shall take due account of such reports or certificates.
- B. The SFDA shall first require the manufacturers, through its **authorized representative** where appropriate, the importers or the distributors to take the appropriate corrective action and ensure proper implementation. Where those actions are not applied or are not sufficient the SFDA shall take safeguard measures, as specified in Implementing Rule MDS- IR 8, to ensure that non-conforming devices are withdrawn from the market or their availability is prohibited or restricted. Furthermore, the SFDA shall take appropriate measures to ensure that potential users of the devices are informed accordingly.

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. The SFDA encourages medical device users, persons involved in the provision of healthcare within the KSA and distributors to report adverse events to both the SFDA and manufacturers. Where the device has been manufactured outside the KSA, communication is through the relevant **authorized representative**. It is the **authorized representative's** duty to ensure the manufacturer of the device receives the report.
3. Implementing Rule MDS-IR 7 on *Post-Marketing Surveillance* (see expert above) provides information on the reporting procedures. The **authorized representative** should refer to MDS – G6 *Guidance on Post-Marketing Surveillance*, available on the SFDA website, for further information on this subject.
4. An important aspect of effective post-market surveillance is the need of the SFDA, health authority, authorized representative and/or distributor to trace an individual medical device through the supply chain. Therefore, the 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.



ANNEX I

**Sample agreement between a single legal
manufacturer and an authorized representative**

S F D A

AGREEMENT FOR AUTHORIZED REPRESENTATIVE SERVICES

Parties to the Agreement:

Manufacturer:

established in [*insert postal address to establish location*].....

and

Authorized Representative:

.....

established in [*insert postal address to establish location*]

.....

A. Definitions

For the purpose of this agreement, the **manufacturer** shall be the natural or legal person responsible for the medical devices he intends to place on the KSA market under his name and for which he already has the necessary authorization to legally place these devices on the market in one of the GHTF Founding Member jurisdiction.

Furthermore, the definitions specified in the Medical Devices Interim Regulation and its Implementing Rules shall apply.

B. Governing Law

This agreement is subject to the laws of the KSA.

C. Applicable Medical Device Regulation

The Interim Regulation for Medical Devices, issued by the Saudi Food and Drug Authority Board of Directors' Decree number 1-8-1429 dated 27 December 2008, published on 17 April 2009 in Umm AL-QURA Journal year 86 issue No 4249 and its relevant Implementing Rules.

D. Tasks of the Authorized Representative

The authorized representative shall:

- a. Represent the manufacturer in its dealings with the SFDA.
- b. List each medical device category or generic device group intended to be supplied to the KSA market. as required by Article 8 of the Implementing Rule MDS IR3 *Medical Devices Listing*.
- c. Access the electronic application form available on the MDMA portion of the SFDA website and provide the SFDA with all necessary supporting documentary evidence, required by CHAPTER II of Implementing Rule MDS – IR 6 *Marketing Authorization*.
- d. Cooperate with the SFDA on evaluations and actions taken during market surveillance and/or vigilance procedures described in Implementing Rule MDS - IR7 *Post-marketing Surveillance*.
- e. Make the following information available to the SFDA when so required in relation to its market surveillance activities:
 - The marketing authorization issued by the SFDA for the listed medical devices.
 - The documentation which was used to demonstrate compliance with the Regulation of the relevant GHTF founding member jurisdictions.

- The documents approved by the SFDA demonstrating compliance with the specific Saudi provisions referred to in Article 6 of Implementing Rule MDS – IR 6 ***Marketing Authorization***.
- f. Inform the SFDA of any adverse events that have occurred outside the KSA but have consequences for medical devices that have been authorized to be placed on the market of the KSA. The authorized representative shall explain the circumstances and provide information on the corrective action the manufacturer has taken or intends to take.
- g. Inform the SFDA of all field safety corrective actions resulting from post-market follow-up investigations performed by the manufacturer for medical devices that have been authorized to be placed on the market of the KSA. The authorized representative shall explain the reason for the corrective action and provide information on the action the manufacturer has taken or intends to take.
- h. Cooperate with parties involved in distribution activities, installation and maintenance of medical devices that have been placed on the KSA market under its mandate.

E. Responsibilities of the Manufacturer

The manufacturer shall:

[List the commitments and responsibilities of the manufacturer that will enable the authorized representative to perform the tasks listed in D in an efficient and effective manner]



F. Medical Devices

The manufacturer designates the authorized representative to act on its behalf for one or more of the medical device categories indicated in the table that follows.

Active implantable devices	Non-active implantable devices
Anaesthetic and respiratory devices	Dental devices
Ophthalmic and optical devices	Electro mechanical medical devices
Hospital hardware	In Vitro Diagnostic medical devices
Reusable devices	Single use devices
Assistive products for persons with disability	Diagnostic and therapeutic radiation devices
laboratory equipment	Healthcare facility products and adaptations
Complementary therapy devices	Biologically derived devices
other categories	
or generic device group as listed below	

G. Termination

This agreement may be terminated by the **manufacturer** at any time provided it:

- a. maintains the continuous presence of an authorized representative to represent it within the KSA. and
- b. provides the authorized representative with a written notice of termination at least 45 days before the event.

This agreement may be terminated by the **authorized representative** at any time provided it:

- a. undertakes to continue with the tasks specified in D until such time as the manufacturer appoints a licensed alternative to represent it within the KSA; and
- b. provides the manufacturer with a written notice of termination at least 90 days before the event.

In the event of the SFDA terminating the authorized representative's license, the authorized representative is expected to continue with the tasks specified in D until such time as the SFDA licenses an alternative authorized representative to represent the manufacturer within the KSA or for 90 days.

H. Other Tasks and Provisions Additional to those Required for Authorized Representative Licensing

[List any tasks additional to those specified in D, that the manufacturer, under its sole responsibility, requires the authorized representative to undertake within the KSA. Such tasks are not assessed by the SFDA when it licenses the authorized representative]

I. Application Date

This agreement shall enter into force on(dd/mm/yyyy).....

J. Term of the Agreement

This agreement shall remain in effect for years from the date of application indicated in I, or until terminated by either party under the provisions of G.

K. Attestation

I, the undersigned, have the authority to accept the delegated tasks to be performed in the KSA, **on behalf of the authorized representative** named above, and ensure written procedures are applied to the tasks, where appropriate.

Name:

Signed:



Position in organization:

Date:

I, the undersigned, have the authority to agree **on behalf of the legal manufacturer** who is party to this agreement, to take without delay all measures necessary to allow the execution of the tasks delegated to the authorized representative.

I, the undersigned, declare that I have not designated any authorised representative other than that who is party to this agreement to act on my behalf for the medical devices listed in Section F.

Name:

Signed:

Position in organization:

Date:

Note:

1. If the legal manufacturer is located outside the Kingdom of Saudi Arabia, the agreement shall be authenticated by all of the following parties:

- A) Chamber of Commerce in foreign country.
- B) The Ministry of Foreign Affairs in foreign country.
- C) The Saudi embassy in the foreign country.
- D) The Saudi Foreign Ministry.

2. If the legal manufacturer is located within the Kingdom of Saudi Arabia, the agreement shall be authenticated by all of the following parties:

- A) Chambers of Commerce and Industry.
- B) The Embassy of the foreign party in the Kingdom.
- C) The Saudi Foreign Ministry.



ANNEX II:

Sample agreement between an organization representing multiple legal manufacturers within a single company and an authorized representative



AGREEMENT FOR AUTHORIZED REPRESENTATIVE SERVICES

Parties to the Agreement:

Organization representing multiple legal manufacturers within a single company:

established in *[insert postal address to establish location]*.....

and

Authorized Representative:

.....
established in *[insert postal address to establish location]*

A. Definitions

For the purpose of this agreement, the **manufacturer** shall be the natural or legal person responsible for the medical devices he intends to place on the KSA market under his name and for which he already has the necessary authorization to legally place these devices on the market in one of the GHTF Founding Member jurisdiction.

Furthermore, the definitions specified in the Medical Devices Interim Regulation and its Implementing Rules shall apply.

B. Governing Law

This agreement is subject to the laws of the KSA.

C. Applicable Medical Device Regulation

The Interim Regulation for Medical Devices, issued by the Saudi Food and Drug Authority Board of Directors' Decree number 1-8-1429 dated 27 December 2008, published on 17 April 2009 in Umm AL-QURA Journal year 86 issue No 4249 and its relevant Implementing Rules.

D. Tasks of the Authorized Representative

The authorized representative shall:

- a. Represent the manufacturer in its dealings with the SFDA.
- b. List each medical device category or generic device group intended to be supplied to the KSA market. as required by Article 8 of the Implementing Rule MDS IR3 ***Medical Devices Listing.***
- c. Access the electronic application form available on the MDMA portion of the SFDA website and provide the SFDA with all necessary supporting documentary evidence, required by CHAPTER II of Implementing Rule MDS – IR 6 ***Marketing Authorization.***
- d. Cooperate with the SFDA on evaluations and actions taken during market surveillance and/or vigilance procedures described in Implementing Rule MDS - IR7 ***Post-marketing Surveillance.***
- e. Make the following information available to the SFDA when so required in relation to its market surveillance activities”
 - The marketing authorisation issued by the SFDA for the listed medical devices.

- The documentation which was used to demonstrate compliance with the Regulation of the relevant GHTF founding member jurisdictions.
 - The documents approved by the SFDA demonstrating compliance with the specific Saudi provisions referred to in Article 6 of Implementing Rule MDS – IR 6 **Marketing Authorization**.
- f. Inform the SFDA of any adverse events that have occurred outside the KSA but have consequences for medical devices that have been authorized to be placed on the market of the KSA. The authorized representative shall explain the circumstances and provide information on the corrective action the manufacturer has taken or intends to take.
- g. Inform the SFDA of all field safety corrective actions resulting from post-market follow-up investigations performed by the manufacturer for medical devices that have been authorized to be placed on the market of the KSA. The authorized representative shall explain the reason for the corrective action and provide information on the action the manufacturer has taken or intends to take.
- h. Cooperate with parties involved in distribution activities, installation and maintenance of medical devices that have been placed on the KSA market under its mandate.

E. Responsibilities of the Legal Manufacturers Subject to this Agreement

The manufacturers shall:

[List the commitments and responsibilities of the manufacturers that will enable the authorized representative to perform the tasks listed in D in an efficient and effective manner]

F. Medical Devices

The manufacturers designate the authorized representative to act on their behalf for one or more of the medical device categories indicated in the table that follows.

Active implantable devices	Non-active implantable devices
Anaesthetic and respiratory devices	Dental devices
Ophthalmic and optical devices	Electro mechanical medical devices
Hospital hardware	In Vitro Diagnostic medical devices
Reusable devices	Single use devices
Assistive products for persons with disability	Diagnostic and therapeutic radiation devices
laboratory equipment	Healthcare facility products and adaptations
Complementary therapy devices	Biologically derived devices
other categories	
or generic device group as listed below	

G. Termination

This agreement may be terminated by the **manufacturer** at any time provided it:

- a) maintains the continuous presence of an authorized representative to represent it within the KSA. and
- b) provides the authorized representative with a written notice of termination at least 45 days before the event.



This agreement may be terminated by the **authorized representative** at any time provided it:

- a) undertakes to continue with the tasks specified in D until such time as the manufacturer appoints a licensed alternative to represent it within the KSA. and
- b) provides the manufacturer with a written notice of termination at least 90 days before the event.

In the event of the SFDA terminating the authorized representative’s license, the authorized representative is expected to continue with the tasks specified in D until such time as the SFDA licenses an alternative authorized representative to represent the manufacturer within the KSA or for 90 days.

H. Other Tasks and Provisions Additional to those Required for Authorized Representative Licensing

[List any tasks additional to those specified in D, that the organization representing the manufacturers listed below, under its sole responsibility, requires the authorized representative to undertake within the KSA. Such tasks are not assessed by the SFDA when it licenses the authorized representative]

I. Application Date

This agreement shall enter into force on(dd/mm/yyyy).....

J. Term of the Agreement

This agreement shall remain in effect for years from the date of application indicated in I, or until terminated by either party under the provisions of G.



K. Attestation

I, the undersigned, have the authority to accept the delegated tasks to be performed in the KSA, **on behalf of the authorized representative** named above, and ensure written procedures are applied to the tasks, where appropriate.

Legal Manufacturer’s Name	Postal Address to Establish Location

Name:

Signed:

Position in organization:

Date:

I, the undersigned, as party to this agreement, have the authority to agree **on behalf of the manufacturers listed below**, for them to take without delay all measures necessary to allow the execution of the tasks delegated to the authorized representative. Moreover, I accept the commitment to ensure each one of the listed manufacturers has a copy of this agreement and is aware of its particular tasks and responsibilities under its provisions. I, the undersigned, declare that I have not designated any authorized representative other than that who is party to this agreement to act on my behalf for the medical devices listed in Section F.

Name:

Signed:

Position in organization:

Date:

Legal Manufacturer's Name	Postal Address to Establish Location

Note:

1. If the legal manufacturer is located outside the Kingdom of Saudi Arabia, the agreement shall be authenticated by all of the following parties:
 - A) Chamber of Commerce in foreign country.
 - B) The Ministry of Foreign Affairs in foreign country.
 - C) The Saudi embassy in the foreign country.
 - D) The Saudi Foreign Ministry.

2. If the legal manufacturer is located within the Kingdom of Saudi Arabia, the agreement shall be authenticated by all of the following parties:
 - A) Chambers of Commerce and Industry.
 - B) The Embassy of the foreign party in the Kingdom.
 - C) The Saudi Foreign Ministry.