المملكة العربية السعودية
الهيئة العامة للغذاء والدواء

Guidance for completing SFDA On-line MDMA Application Form (Part 1) European Jurisdiction

قطاع الأجهزة والمنتجات الطبية
إدارة الإذن بالتسويق

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V2.2

Document History

Version	Modification	date
1.0	Initial draft	26-06-2012
2.0	Update the information to be comply with the second version of MDMA	07-02-2013
2.1	Updates following first review	22-12-2013
2.2	Minor updates following third review	29-03-2015

1. Manufacturer

No	SFDA Question	***DO*** ***CHECK*** ***WARNING***	***Task***
1.1	Manufacturer	*DO*	*Select the name of the Manufacturer*
1.2	Legal Manufacturer	*DO*	*Select the name and address of the Manufacturer.*
		CHECK	*The name and address of the Manufacturer of the devices in this application. It must concur with sections:* *2.1.10 Labelling* *2.1.11 IFU,* *2.3 A/C power supply statement – if applicable* *2.4 Environmental statements* *2.5 The provided documents in this section* *5.3 EC Certificates* *5.3 Recent Audit Report* *5.3 Other Certificates as required by the device class* *5.4 Declaration of Conformity* *6.3 QMS Certificate* *7.1 Regulatory Compliance Attestation*
		WARNING	*A common error is to select the device manufacturing site address, rather than the Manufacturer address* *If the Manufacturer has two addresses, a Postal Address and a Site Address, please provide an attested letter from the Manufacturer explaining that there are two addresses. – Insert the letter in section 2.1.10*
1.3	Medical Device Category	*DO*	*Use SFDA drop-down list of 17 categories*

2. General Info.

No	SFDA Question	***DO*** ***CHECK*** ***WARNING***	***Task***
2.1	Details of the medical devices applying for market authorisation	*DO*	*Insert the list of devices in the application* *For IVD, List the kit as a single item in section 2.1. For Labels & IFU, all the labels of the reagents in the kit must be provided*
		CHECK	*Cross check the list of devices against* *labels (2.1.10)* *IFU (2.1.11)* *Declaration of Conformity (5.4)* ***Refer to SFDA BUNDLING Rules in MDS-G7:*** *http://www.sfda.gov.sa/en/medicaldevices/regulations/DocLib/MDS-G7.pdf*

<table>
<tr><th>No</th><th>SFDA Question</th><th>DO
CHECK
WARNING</th><th>Task</th></tr>
<tr><td></td><td></td><td></td><td>If a device has multiple models, for example Male Urinary Catheters of different sizes, the applicant should include these in one line.

<table><tr><td>Product Description</td><td>Intended Purpose</td><td>Trade/Brand Name</td><td>Model Number</td></tr><tr><td>Male Urinary Catheters</td><td>Drain urine from the bladder</td><td>XYZ</td><td>123-40
123-50
123-60</td></tr></table></td></tr>
<tr><td></td><td></td><td></td><td></td></tr>
<tr><td>2.1.1</td><td>Product Brief Description
(This field will appear on the MDMA printout)</td><td>DO</td><td>Insert the Product Brief Description

Note: The Product Description will be printed on the MDMA License issued by the SFDA.</td></tr>
<tr><td></td><td></td><td>CHECK</td><td>The Product Description must be precise and informative (maximum of 100 characters with spaces).
In English only, no commas (acceptable if it makes sense (part of the sentence) ex.: infant, paediatric & adult ventilator), clear and accurate.
No spelling errors
No Product Names or Company Names</td></tr>
<tr><td></td><td></td><td>WARNING</td><td>“Catheter, Urinary” will be rejected whereas “Urinary Catheter” is acceptable

Do Not include Brand Names or Company Names</td></tr>
<tr><td>2.1.2</td><td>Intended purpose of the medical device type</td><td>DO</td><td>Insert the intended purpose.</td></tr>
<tr><td></td><td></td><td>CHECK</td><td>Typically this is an extract from the IFU</td></tr>
<tr><td>2.1.3</td><td>Product Trade/Brand Name (As it appears on the label). (This field will appear on the MDMA printout)</td><td>DO</td><td>Insert the product Trade/Brand Name

Note: The product Trade/Brand Name will be printed on the MDMA License issued by the SFDA.</td></tr>
<tr><td></td><td></td><td>CHECK</td><td>Check it concurs with the product Trade/Brand Name as it appears on the product Label</td></tr>
<tr><td>2.1.4</td><td>Model Name/Number (As it appears on the label)</td><td>DO</td><td>Insert the Model Name/Number</td></tr>
<tr><td></td><td></td><td>CHECK</td><td>If more than one Model Number is listed in a window, these models should only differ in either colour, size, weight, dimensions, shape or quantity.</td></tr>
<tr><td></td><td></td><td>WARNING</td><td>If the product has a model/Ref number, the brand name must not be repeated in this section</td></tr>
<tr><td>2.1.5</td><td>Manufacturer’s Device Identifier Number</td><td>DO</td><td>Insert the Manufacturers Device Identifier Number</td></tr>
<tr><td></td><td></td><td>CHECK</td><td>Typically this is the REF number, or Product catalogue number

Check it concurs with the product ID number as it appears on the product Label</td></tr>
</table>

<table>
<tr><th>No</th><th>SFDA Question</th><th>DO
CHECK
WARNING</th><th>Task</th></tr>
<tr><td>2.1.6</td><td>Format of medical device identifier number(s) that will appear on labelling for traceability purposes</td><td>DO</td><td>Insert the Format of medical device identifier number(s) that will appear on labelling <u>for traceability purposes</u></td></tr>
<tr><td></td><td></td><td>CHECK</td><td>Typically this is the LOT number, or Serial number
Provide a brief description of how the number is formatted
e.g. LOT YYYY-MM-DD (year-month-day)</td></tr>
<tr><td>2.1.7
2.1.8
2.1.9</td><td>Nomenclature code number
GMDN
UMDNS
Other (e.g. FDA identification number, JMDN</td><td>DO</td><td>Insert the nomenclature code number if available</td></tr>
<tr><td></td><td></td><td></td><td></td></tr>
<tr><td>2.1.10</td><td>Provide the label(s) affixed to the device or its wrappers when it is supplied to the KSA.</td><td>DO</td><td>Attach the device labels for ALL devices listed in section 2.1

A/C Power Supply
If the product is connected to an A/C power supply, the applicant must provide images of the power supply label, so it can be cross-checked with the A/C Power Supply signed declaration provided in section 2.3 (60 Hz supply at nominal values of either 230 or 400 volts)

For IVD Kits, all the individual reagent labels must be provided.

All labels must be in compliance with EU MDD/IVDD and national provisions.</td></tr>
<tr><td></td><td></td><td>CHECK</td><td>Labels are provide for ALL devices listed in section 2.1

Including each of the model numbers/REF/Part No./etc

When the device has a range (eg sizes) then
a representative label for each brand name is acceptable with a table that clearly links one product-size to one product ID number.

Example (Acceptable)
<table>
<tr><td>Trade Name</td><td>REF
(Product ID Number)</td><td>Size
(product variable)</td></tr>
<tr><td>Medical Device</td><td>1234</td><td>5x5cm</td></tr>
<tr><td>Medical Device</td><td>1236</td><td>10x10cm</td></tr>
</table>
The applicant has provided a clear link between each of the product ID numbers and the product sizes, colours, dimensions, quantity, shapes or weights.

The table must be from the Manufacturer and must be signed, job title & dated

The Labels must contain:
- Device Trade Name (see 2.1.3)
- Device model/ ID Number (REF)/ (see 2.1.4 and 2.1.5)</td></tr>
</table>

<table>
<tr><th>No</th><th>SFDA Question</th><th>DO
CHECK
WARNING</th><th>Task</th></tr>
<tr><td></td><td></td><td></td><td>- Manufacturers Name & Address (see 1.2)
- CE Mark
- Notified Body Number – if applicable (see 5.2)

In addition it should also contain where applicable:
- The traceability method: LOT or Serial Number
- Power Supply (60 Hz supply at nominal values of either 230 or 400 volts)
- Storage Temperature
- Expiry Date
- Year of Manufacturing
- Sterile & Method
- EC REP Name & Address (see below)
- Single Use
- IVD – if applicable
- IVD Self Test

Note: EU REP: Name & Address:
Required for products where the manufacturer does not have a registered place of business in the EU countries. The EU REP must be printed on the sales packaging (label and/or outer packaging and /or IFU).
Reference:
MDD 93/42/EEC Annex I section 13.3(a).
AIMD 90/385/EEC Annex I section 14.2
IVDD 98/79/EEC Annex I section 8.4

Note: If the device is a Self Test IVD
This MUST BE CLEARLY STATED ON THE LABEL
Reference: IVDD 98/79 Annex I, 8.4(k)

Note: If the device is for Professional Use only
The label in English only is acceptable
Reference: SFDA MDS-IR6 Article 9 (C)

Note: If the device is for Home Use / Self Test IVD
The label must be in both English & Arabic
Reference: SFDA MDS-IR6 Article 9 (C)</td></tr>
<tr><td></td><td></td><td>WARNING</td><td>A common error is wrong or missing labels</td></tr>
<tr><td></td><td></td><td>WARNING</td><td>Tables-
Example (Not Acceptable)
<table>
<tr><td>Trade Name</td><td>REF
(Product ID Number)</td></tr>
<tr><td>Medical Device</td><td>1234
1236
etc</td></tr>
</table>
The applicant has provided no link between the product ID numbers and the product sizes, colours, dimensions, quantity, shapes or weights.

The label shall not include the SFDA logo, SFDA name or MDMA license number.</td></tr>
<tr><td></td><td></td><td></td><td></td></tr>
<tr><td>2.1.11</td><td>Provide the ‘instructions for use’ document intended for KSA users</td><td>DO</td><td>Attach the IFU for ALL the devices listed in section 2.1

This is a Europe submission therefore the IFU must be in</td></tr>
</table>

No	SFDA Question	*DO* *CHECK* *WARNING*	*Task*
	of the medical device. - If NOT RELEVANT provide a justification*.		*compliance with EU MDD/IVDD and national provisions.*
		CHECK	*- IFU cover ALL the devices Trade/Brand Names listed in section 2.1* *- All the IFU are CE Marked* *- Manufacturers name and address is printed on the IFU and concurs with section 1.2* *- Note: EU REP: Name & Address:* *Required for products where the manufacturer does not have a registered place of business in the Community. The EU REP must be printed on the sales packaging (label and/or outer packaging and /or IFU).* *Reference:* *MDD 93/42/EEC Annex I section 13.3(a).* *AIMD 90/385/EEC Annex I section 14.2* *IVDD 98/79/EEC Annex I section 8.4* ***- Note: If the device is for Professional Use only*** *The IFU in English only is acceptable* *Reference: SFDA MDS-IR6 Article 9 (C)* ***- Note: If the device is for Home Use / Self Test IVD*** *The IFU must be in both English & Arabic* *Reference: SFDA MDS-IR6 Article 9 (C)* *- Any warnings and/or precautions to take.* *- The IFU must have Date of Issue or the latest Revision Number* *Reference:* *MDD93/42/EEC Annex I 13.6(q)* *98/79EC IVDD Annex I 8.7(u)* *90/385 EC AIMD Annex I 15* *- Device models and IDs (must match with 2.1 – if mentioned). If the IFU does not cover all models or IDs or does not match with sections 2.1.4 and 2.1.5, a justifications* is required.* *- Storage Temp: Min & Max (where required)* *- Sterility method:(where required)* *- Single use: (where required)* *- Power requirement if applicable (60 Hz supply at nominal values of either 230 or 400 volts).*
		WARNING	*A common error is a wrong, missing information or missing IFU*
	If NOT RELEVANT provide a justification*	*DO*	*If its NOT RELEVANT to have an IFU for the product, then the applicant MUST provide a justification*.*

No	SFDA Question	*DO* *CHECK* *WARNING*	*Task*
		CHECK	*The justification* must be from the Manufacturer and must be signed, job title & dated*
		WARNING	*The justification* must be from the Manufacturer and must be signed, job title & dated*
2.1.12	**List of Accessories**	***DO***	***List the Accessories for this device***
		CHECK	***Definition: Accessories are devices specifically intended by its Legal Manufacturer to be used together with the medical device to achieve its intended purpose.***
		WARNING	***If the Accessory can be used as a stand-alone medical device, the SFDA do NOT consider it an Accessory. It must be listed as a Medical Device***
2.1.12.1 To 2.1.12.11		***DO***	***Same requirements as sections 2.1.1 to 2.1.11***
2.2	Jurisdiction(s) where this medical device may be placed on the market. • Australia • Canada • Europe • Japan • USA	*DO*	*Make the selections as appropriate.*
		CHECK	*By minimum, Europe must be selected because this is a European submission*
2.3	If the device is connected to an a/c power supply, provide a statement that confirms it is: 1. designed to operate with a 60 Hertz supply at nominal values of either 230 or 400 volts; 2. is fitted with the appropriate a/c power connector; 3. maintains the required electrical safety conditions 4. continues to perform to specification.	*DO*	*If it is not applicable select the (N/A) box and move to the next section.* *If the device/accessory is connected to an a/c power supply, complete the statement Template provided* ***Printed on the <u>Manufacturer's</u> Letterhead*** *The statement must be from the Manufacturer and must be signed, job title & dated*
		CHECK	*The statement must be from the Manufacturer (Letterhead) and must be signed, job title & dated*
		WARNING	*The statement must be from the Manufacturer and must be signed, job title & dated* *Do not alter the wording of the SFDA Template*
2.4	Provide a statement that	*DO*	*Complete the statement Template provided*

No	SFDA Question	*DO* *CHECK* *WARNING*	*Task*
	the device will perform as intended when subjected to other environmental factors encountered within the KSA		***Printed on the <u>Manufacturers</u> Letterhead*** *The statement must be from the Manufacturer (Letterhead) and must be signed, job title & dated*
		CHECK	*The statement must be from the Legal Manufacturer and must be signed, job title & dated*
		WARNING	*The statement must be from the Manufacturer and must be signed, job title & dated* *Do not alter the wording of the SFDA Template*
2.5	Provide a copy of the manufacturer's instructions to ensure that the medical device intended to be placed on the KSA market will be correctly stored, transported, installed, maintained & disposed of, and that users can be trained in their proper use and maintenance.	*DO*	*Provide a copy of the manufacturer's instructions to ensure that the medical device intended to be placed on the KSA market will be correctly stored, transported, installed, maintained & disposed of, and that users can be trained in their proper use and maintenance.* *The applicant may also provide additional information that they believe is relevant to this request. The additional information must be from the Manufacturer (Letterhead) and must be signed, job title & dated, and only list devices and accessories Trade/Brand Name in this application(see 2.1) or the application number.*
2.6	Provide a copy of the manufacturers advertising and marketing material intended for use in the KSA	*DO*	*Attach a copy of the marketing literature for at least ALL the devices listed in section 2.1* *Note: It is acceptable for the marketing material to include more devices than is listed in section 2.1* *Note: A product catalogue (soft copy "online or offline" or hard copy) is considered marketing material and is acceptable.*
		CHECK	*Marketing literature is provided for at least ALL the devices listed in section 2.1* *It is acceptable for the marketing material to include more devices than listed in section 2.1* *The marketing literature must include the name of Manufacturer* *Note: It is not necessary to have the address of the Manufacturer on the marketing literature* *The marketing material must contain the document control reference number* ***Note: If the device is for Professional Use only*** *The marketing literature in English only is acceptable* *Reference: SFDA MDS-IR6 Article 9 (F)*

No	SFDA Question	*DO* *CHECK* *WARNING*	*Task*
			Note: If the device is for Home Use / Self Test IVD *The marketing literature must be in both English & Arabic* *Reference: SFDA MDS-IR6 Article 9 (F)*
		WARNING	*A common error is to state there is no marketing literature when a product catalogue is available* *A common error is to provide a marketing material without a document control reference number* *Another common error is to state there is no marketing literature when the Manufacturers webpage, which is accessible in the Kingdom of Saudi Arabia, contains marketing literature for the devices listed in the application.*
	• if NOT AVAILABLE provide an explanation and the date when such material will become available	*DO*	*if NOT AVAILABLE provide both an explanation and the date when such material will become available* *Note: A product catalogue (soft copy "online or offline" or hard copy) is considered marketing material and is acceptable.*
		CHECK	*The explanation must be from the Legal Manufacturer (Letterhead). It must state why the marketing literature is currently not available. It must state when (date) it will become available. The explanation must be signed, job title and dated.*
	• If NOT REQUIRED provide a justification*	*DO*	*If NOT REQUIRED provide a justification** *Note: A product catalogue (on-line or printed) is considered marketing material and is acceptable.*
		CHECK	*The justification* must be from the Manufacturer (Letterhead) and must be signed, job title and dated*

3. Jurisdiction

No	SFDA Question	*DO* *CHECK* *WARNING*	*Task*
3.1	Desired Jurisdiction	*DO*	*Ensure the European jurisdiction has been selected*

4. Product Categories (Europe)

No	SFDA Question	*DO* *CHECK* *WARNING*	*Task*
4.1	Device Type • Medical Device • AIMD • IVD	*Do*	*Select one option*
		CHECK	*The selected Device Type is correct for the devices listed in section 2.1*
4.2	Device Classification	*DO*	*Select one option*

	Medical Devices • Class I • Class IIa • Class IIb • Class III IVD • Annex II List A • Annex II List B • Self Test • Others		
		CHECK	*The selected Device Classification is correct for the devices listed in section 2.1* *The Device Classification concurs with that stated in the Declaration of Conformity section 5.4*
4.3	Class I (only) Sterile Device	*DO*	*Select one option* *Note: Section 4.3 is only available if the device is Class I*
		CHECK	*If Yes has been selected then the CE Mark will have a Notified Body number* *The CE Mark & Notified Body number on sections:* *2.1.10 Labels* *2.1.11 IFU* *5.2 The Notified Body name and number information has been provided* *5.3 The EC Certificate and most recent Audit report (less than 1 year old) has been provided.*
4.4	Class I (only) Measuring Device	*DO*	*Select one option* *Note: Section 4.4 is only available if the device is Class I*
		CHECK	*If Yes has been selected then the CE Mark will have a Notified Body number* *The CE Mark & Notified Body number on sections:* *2.1.10 Labels* *2.1.11 IFU* *5.2 The Notified Body name and number information has been provided* *5.3 The EC Certificate and most recent Audit report (less than 1 year old) has been provided.* *The measuring function must be expressed in legal units & The limits of accuracy must be indicated by the manufacturer. Reference: MDD/93/42 EEC Annex I (10)*

5. Product Verification (Europe)

No	**SFDA Question**	***DO*** ***CHECK*** ***WARNING***	***Task***
5.1	Indicate the Annex(es)	*DO*	*Select the applicable Annex(es).*

No	SFDA Question	*DO* *CHECK* *WARNING*	*Task*
	from the EU directive applied to the device to establish conformity to EU regulations		
		CHECK	*The selected Annex(es) concurs with sections:* *5.3 EC Certificate* *5.4 Declaration of Conformity*
5.2	Provide the name and reference number of the Notified Body responsible for issuing the certificates, decisions or reports required by the conformity assessment Annex(es) referred to above, if any	*DO*	*Insert the Notified Body name and number* *However, if the device is a Medical device Class I non-sterile & non-measuring devices or General IVD, leave this section blank. This class of device does not require the involvement of a Notified Body*
		CHECK	*The Notified Body name & number concurs with sections:* *2.1.10 Labels* *2.1.11 IFU* *5.3 EC Certificate* *5.3 Audit Report* *5.3 Design Certificate – if applicable* *5.4 Declaration of Conformity* *Confirm that the Notified Body has a current and valid accreditation to issue these Certificates & Reports*
5.3	Provide a copy of the current certificates as required by the indicated conformity assessment Annex. Provide a copy of the most recent reports issued by the Notified Body which is related to the provided certificate.	*DO*	*Note: For Medical Devices Class I non-sterile & non-measuring devices or General IVD leave this section blank and select both (N/A) boxes. These classes of devices do not require the involvement of a Notified Body* *For all other devices insert* *1.Valid EC Certificate(s) according to selecting rout for the Manufacturer and cover(s) the applied devices.* *2. Most recent Certification/ Surveillance/ Recertification Audit Report (less than 1 year old) of the Manufacturer.* *3. If the audit is more than one year old, a justification* is required from the notified body to confirm the provided audit report is the most recent one.* *-The report must be in English (translations must be issued and attested by the notified body or an independent translator)* *-The report scope must include the EC Directive MDD/93/42/EEC* *-The report must be of the Legal Manufacturer* *-The report must be complete* *-The report must be less than 1 year old* *-The report must be signed by the auditor* *-The report must recommend continuation of certification* *CORRECTIVE ACTIONS -Please note that if the Auditor withholds the recommendation for continuation of certification until the corrective actions have been completed then the SFDA require evidence from the Notified Body that the*

No	SFDA Question	*DO* *CHECK* *WARNING*	*Task*
			Notified Body are satisfied with the corrective actions and recommends continuation of certification. *In addition For List A IVD* *Insert a recent batch release report covering each List A IVD device listed in section 2.1* *The SFDA will require confirmation from the Notified Body that the batch release report is acceptable.* *Note: The MDMA License issued by the SFDA will expire:* *Class I devices – 3 years* *Class IIa & IIb – EC Certificate expiry date* *Class III/AIMD/List A IVD/ Self Test IVD – EC Certificates Expiry, whichever is earliest.* *Reference: SFDA Announcement 12/10/MDS-AN003*
		CHECK	*The EC Certificate, Audit Report & Design Examination Certificate (if applicable) are related to the Manufacturer and products in section 2.1*
		WARNING	*The SFDA require a copy of the most recent Certification/ Surveillance/ Recertification audit report (less than 1 year old) in order to confirm that the EC Certificates are still current & valid.* *If the most recent Audit Report is more that 1 year old, the applicant must provide a justification* issued by the Notified Body stating that the provided audit report is the most recent one & the certificate is valid.* *A common error is to provide an UNSIGNED letter from the Notified Body.* *A common error is not to include the most recent Audit Report* *A common error is to provide the Certificates & Audit reports for the makers of the device (subcontractors) and not the Manufacturer.*
5.4	Provide a copy of the manufacturers current EC Declaration of Conformity	*DO*	*Insert a Declaration of Conformity (DOC) for at least ALL the devices listed in section 2.1* *Note: It is acceptable for the Declaration of Conformity to include more devices than what are listed in section 2.1.*
		CHECK	*Contents of a typical Declaration of Conformity* • *Device trade name and model number* • *Device classification* • *Notified Body name and ID number (if applicable)* • *EC certificate number (if mentioned)* • *Date CE Marking was first applied (if mentioned)* • *EC-REP Authorized Representative name & address (if mentioned – see below)* • *Route to compliance Directive & Annex*

No	SFDA Question	*DO* *CHECK* *WARNING*	*Task*
			• *Standards applied (optional)* • *Manufacturer name & address* • *Signed* • *Job title (appropriate member of the Manufacturer)* • *Dated* *Reference: EC-REP:* *MDD 93/42/EEC Annex I section 13.3(a).* *AIMD 90/385/EEC Annex I section 14.2* *IVDD 98/79/EEC Annex I section 8.4*
		WARNING	*A common error is to provide a Declaration of Conformity that does not cover all devices in section 2.1.*
5.5	Indicate whether the device design has changed in a manner that could affect safety and/or performance since the manufacturer declared the device in conformity with the EU directive? • Yes • No	*DO*	*Select one answer*
5.6	If the device is a Class I medical device, or General IVD medical device, indicate: (a) The name of the Regulatory Authority with whom the manufacturer has registered the device (b) Provide evidence of registration	*DO*	*Note: If the device is NOT Class I or General IVD leave this section blank.* *Note: All Class I devices including sterile and/or measuring devices and General IVD must complete this section* *Provide the name and address Regulatory/Competent Authority with whom the manufacturer or the EU REP has registered the device* *Provide evidence of registration of ALL devices listed in section 2.1*
		CHECK	*The evidence includes:* *The name and address of the Regulatory/Competent Authority* *The name and address of the Manufacturer or EC REP & ALL devices listed in section 2.1* *Free Sales Certificate issued by the Regulatory/Competent Authority*
		WARNING	*The evidence of registration must come from the Regulatory/Competent Authority* *A common error is not to include all devices listed in section 2.1*

6. Manufacturers QMS Status (EUROPE)

No	SFDA Question	*DO* *CHECK* *WARNING*	*Task*
6.1	Indicate whether the manufacturer of the medical device operates an established quality management system (QMS). • Yes • No	*DO*	*Select one answer*
6.2	If YES, indicate the QMS standard used	*DO*	*Insert the Quality Management Standard (Example: ISO 13485)*
6.3	Provide a copy of all the current quality management approvals/ certificates held by the manufacturer that relate to the device that is in this application.	*DO*	*Insert the Manufacturers valid QMS approvals/certificates*
		CHECK	*The QMS Certificates are:* *QMS Certificate scope covers all devices listed in section 2.1* *Issued to the Manufacturer of the devices* *Applied Standard listed in section 6.2* *The QMS Certificate is still current & valid*
		WARNING	*The QMS Certificate Scope must cover all devices listed in section 2.1.* *The QMS Certificate is current & valid*
6.4	Description of the medical devices covered by the QMS	*DO*	*Insert a description of the medical devices covered by the QMS*
		CHECK	*The description concurs with the QMS Certificate submitted in section 6.3 AND the devices listed in section 2.1*
6.5	Indicate the procedures that are included within the Manufactures QMS • Design & development • Manufacturing • Final product testing • Manufacture of sterile devices	*DO*	*Select the procedures that are included within the Scope of the Manufactures QMS*
		CHECK	*The procedures selected are within the scope of the QMS Certificate submitted in section 6.3* *For sterile product, "Manufacturing of sterile devices" should be selected.*

7. Other National Provisions

No	SFDA Question	*DO* *CHECK* *WARNING*	*Task*
7.1	Provide a attestation, written in English, to declare that each clearly identified medical device covered in this application complies with the medical device regulations that apply within the GHTF Founding Member jurisdiction that has been selected as the basis of the application and with the specific KSA national provisions within the Medical Devices Interim Regulation. (SFDA Template provided)	*DO*	*Complete the attestation using the template provided* *The attestation must be printed on the* ***Manufacturers Letterhead*** *GHTF Regulation: Select EU for EU based application.* *Manufacturer name & address* *Signed:* *Job Title:* *Dated:*
		CHECK	*Only Europe has been selected as the GHTF Regulation.* *The attestation must be from the Manufacturer and must be signed, job title & dated*
		WARNING	*Print on the Manufacturers Letterhead* *This is a European submission, therefore only Europe must be selected.*
7.2	Provide the address of the location where the manufacturer holds technical information to support this attestation.	*DO*	*Provide the address of the location where the Manufacturer holds technical information to support this attestation.*
		CHECK	*It must be a full postal address (ex: building number, road, city, postal code, state, country)*
7.3	Signature of the person responsible for completing this application (A)	*DO*	*Complete the attestation using the SFDA template provided* *The attestation must be printed on the* ***Authorised Representative (AR)/ Local Manufacturers (LM) Letterhead*** *Application Number:* *AR/LM Company name & address matching MDNR information in English (Arabic and English is acceptable):* *Signed:* *Job Title:* *Dated:* *AR ID Number:*
		CHECK	*The correct application number has been provided.*

No	SFDA Question	*DO* *CHECK* *WARNING*	*Task*
			The name & address of the AR or LM has been provided And the attestation signed, job title and dated *The date of the attestation must not be older than one month from the date of submitting the application*

Notes:

* All justifications are subject to SFDA evaluation.

** 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. (*MDS- G5*)

-END-