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

Revision: 17-Dec-2012

1. Manufacturer

No	SFDA Question	***DO*** ***CHECK*** ***WARNING***	***Task***
1.1	Manufacturer	*DO*	*Insert the name of the Manufacturer*
1.2	Manufacturer Site	*DO*	*Insert 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:* *2.3 Labelling* *2.4 IFU,* *2.5 A/C power supply statement – if applicable* *2.6 Environmental statements* *5.3 EC Certificate* *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 insert the device manufacturers 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 2.3*
1.3	Medical Device Category	*DO*	*Use SFDA drop-down list of 16 categories*
		CHECK	*That all the devices in the application fall under the selected category.* ***Note on SFDA BUNDLING Rules*** *Products must have the same:* *1. Purpose* *2. Technical Performance* *3. Classification*
		WARNING	*A common error is to insert one or more devices in section 2.1 that do not fall under the category selected in 1.3.*

2. General Info.

No	SFDA Question	***DO*** ***CHECK*** ***WARNING***	***Task***
2.1	Details of the medical devices applying for market authorisation (open the list below)	*DO*	*Insert the list of devices in the application*
		CHECK	*Cross check the list of devices against* *labels (2.3)* *IFU (2.4)* *Declaration of Conformity (5.4)*

<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>Note on SFDA BUNDLING Rules
Products must have the same:
1. Purpose
2. Technical Performance
3. Classification

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>WARNING</td><td>A common error is to insert the wrong devices that appear in other sections of the applications</td></tr>
<tr><td></td><td></td><td>WARNING</td><td>A common error is to omit devices that appear in other sections of the applications</td></tr>
<tr><td></td><td>Product Description</td><td>DO</td><td>Insert the Product 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).
In English only.
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></td><td>Intended purpose of the medical device type (mandatory)</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></td><td>Trade/Brand Name (as it appears on the original approval/ authorisation)</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></td><td></td><td>WARNING</td><td>The combination of the Product Description and Trade/Brand Name must be unique for every device listed in the application.</td></tr>
<tr><td></td><td>Model Number (as it appears on the original approval/ authorisation)</td><td>DO</td><td>Insert the Model Number</td></tr>
</table>

No	SFDA Question	*DO* *CHECK* *WARNING*	*Task*
		CHECK	*If more than one Model Number is listed in a window, these models should only differ in either colour, size, weight or dimensions.*
	Manufacturer's Device Identifier Number (mandatory)	*DO*	*Insert the Manufacturers Device Identifier Number*
		CHECK	*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*
	Format of medical device identifier number(s) that will appear on labelling for traceability purposes	*DO*	*Insert the Format of medical device identifier number(s) that will appear on labelling for traceability purposes*
		CHECK	*Typically this is the LOT number, or Serial number* *Provide a brief description of how the number is formatted* *Eg LOT YYYY-MM-DD (year-month-day)*
	Nomenclature code number GMDN UMDNS Other (e.g. FDA identification number, JMDN	*DO*	*Insert the nomenclature code number if available*
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	*Europe must be selected because this is a European submission*
2.3	Provide the label(s) affixed to the device or its wrappers when it is supplied to the KSA.	*DO*	*Attach the device labels for ALL the 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 2.5* *This is a Europe submission therefore the labels must be CE Marked.* *For IVD Kits, all the individual reagent labels must be provided.*

<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>For devices containing PHTHALATES, the device must be appropriately labelled
Reference: MDD/93/42/EEC Annex I (7.5)</td></tr>
<tr><td></td><td></td><td>CHECK</td><td>Labels are provide for ALL the 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 is acceptable provided there is also a table provided 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/dimensions

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

The Labels must contain:
Device Trade Name (see 2.1)
Device ID Number (REF) (see 2.1)
Manufacturers Name & Address (see 1.2)
CE Mark
Notified Body Number – if applicable (see 5.2)

In addition it may also contain:
LOT or Serial Number
Power Supply – if applicable
Storage Temperature
Expiry Date
Date of Manufacture
Sterile & Method – if applicable
EC REP Name & Address – if applicable (see below)
Single Use – if applicable
IVD – if applicable
IVD Self Test – if applicable

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 a Self Test IVD
This MUST BE CLEARLY STATED ON THE LABEL
Reference: IVDD 98/79 Annex I, 8.4(k)</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>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/dimensions.</td></tr>
<tr><td></td><td></td><td></td><td></td></tr>
<tr><td>2.4</td><td>Provide the ‘instructions for use’ document intended for KSA users of the medical device.
- If NOT RELEVANT provide a justification.
(See below)</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 CE Marked.</td></tr>
<tr><td></td><td></td><td>CHECK</td><td>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)

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</td></tr>
</table>

No	SFDA Question	*DO* *CHECK* *WARNING*	*Task*
		WARNING	*A common error is a wrong 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.*
		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*
2.5	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 Herz 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*	*Complete the statement Template provided* *Leave this section blank if it is not applicable and move to the next section.* *If the device is connected to an a/c power supply, complete the statement Template provided* ***Printed on the <u>Manufacturers</u> Letterhead*** *Only list of the devices in the application (see 2.1):* *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	*If the voltage or Hz values on the labels submitted in section 2.3 are outside those listed in the template provided in this section (2.5) a justification will be required.* *The justification must be from the Manufacturer and must be signed, job title & dated* *Do not alter the wording of the Template*
2.6	Provide a statement that the device will perform as intended when subjected to other environmental factors encountered within the KSA	*DO*	*Complete the statement Template provided* ***Printed on the <u>Manufacturers</u> Letterhead*** *Only list of the devices in the application (see 2.1):* *The statement must be from the Manufacturer (Letterhead) and must be signed, job title & dated*
		CHECK	*The name & address of the Manufacturer has been provided* *Only list the devices Trade/Brand Name in this application (see 2.1)*

No	SFDA Question	*DO* *CHECK* *WARNING*	*Task*
		WARNING	*Common error is to include extra devices that are not listed in section 2.1* *Do not alter the wording of the Template*
2.7	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*
2.8	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 (on-line or printed) 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* *Document control reference:* ***Note: If the device is for Professional Use only*** *The marketing literature in English only is acceptable* *Reference: SFDA MDS-IR6 Article 9 (F)* ***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	*Include marketing literature for at least all the devices listed in section 2.1* *Include the Name of the Manufacturer* *Include a document reference number* *A common error is to state there is no marketing literature when a product catalogue is available*

No	SFDA Question	*DO* *CHECK* *WARNING*	*Task*
			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 (on-line or printed) is considered marketing material and is acceptable.*
	• 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*
2.9	Provide a statement to confirm the applicant organisation agrees to report to the SFDA's National Centre of Medical Devices Reporting (NCMDR), any Field Safety Corrective Action that may affect medical devices supplied to the KSA	*DO*	*Complete the statement Template provided* *Depending on the applicant* ***Printed on Authorised Representative (AR) or Local Manufacturer (LM) Letterhead*** *AR/LM Company Name & Address* *Include the AR/LM Company Name & Address* *Include the details of the person signing the statement.* *Name:* *Job Title:* *Signed:* *Dated:*
		Warning	*Do not alter the wording of the Template*

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:* *2.3 Labels* *2.4 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:* *2.3 Labels* *2.4 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*	*Insert the Annex has been selected.*

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 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 Class I non-sterile & non-measuring devices 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:* *2.3 Labels* *2.4 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 current valid accreditation to issue these Certificates & Reports*
		WARNING	*If the Notified Body no longer has a current valid accreditation to issue the certificates & reports submitted in this application, a justification will be required from the applicants new Notified Body. Submit this justification in section 5.3.*
5.3	Provide a copy of the current certificate and most recent reports issued by this Notified Body as required by the indicated conformity assessment Annex	*DO*	*Note: For Class I non-sterile & non-measuring devices leave this section blank. This class of device does not require the involvement of a Notified Body* *For all other devices insert* *1.Valid EC Certificate of the Manufacturer and* *2. Most recent Audit Report (less than 1 year old) of the Manufacturer.* *The audit report is required to verify that the Notified Body issued certificates are current and valid.* *A summary audit report or letter from the Notified Body may be acceptable provided it verifies that the 'current certificates' are both current and valid.* *In addition For Class III devices /AIMD /List A IVD/Self Test (Annex III.6)* *Insert the current Design Examination Certificate* *In addition For List A IVD* *Insert a recent batch release report covering each List A IVD device listed in section 2.1*

No	SFDA Question	*DO* *CHECK* *WARNING*	*Task*
			The SFDA will require confirmation from the Notified Body that the batch release report is acceptable. *If confirmation is not issued by the Notified Body, then the SFDA will require a copy of the contract between the applicant & the Notified Body* *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 Certificate or Design Examination Certificate Expiry, which ever is earliest.* *Reference: SFDA Announcement 12/10/MDS-AN003*
		CHECK	*The EC Certificate, Audit Report & Design Examination Certificate (if applicable) are from the Manufacturer*
		WARNING	*The SFDA require a copy of the most recent 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* *A common error is not to include the most recent Audit Report* *A common error is to provide the Certificates & Audit reports from the makers of the device (subcontractors) and not the Manufacturer.* *There must be at least 1 month validity remaining on the Certificates to allow the SFDA time to process the application.*
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 is listed in section 2.1.*
		CHECK	*Contents of a typical Declaration of Conformity* • *Device trade name and model number* • *Device classification (Class and Rule)* • *Notified Body name and ID number (if applicable)* • *CE certificate number (if applicable)* • *Date CE Marking was first applied* • *EC-REP Authorized Representative name & address (if applicable – see below)* • *Route to compliance Directive & Annex* • *Standards applied (optional)* • *Manufacturer name & address* • *Signed* • *Job title (appropriate member of the Manufacturer)* • *Dated*

No	SFDA Question	*DO* *CHECK* *WARNING*	*Task*
			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 omit the Declaration of Conformity for a device listed in section 2.1* *A common error is the omission of the Job Title of the person signing the Declaration of Conformity*
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* *If YES is selected, please upload in section 5.4 a justification from the Manufacturer (signed, job title & dated)*
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 must complete this section* *Provide the name and address Regulatory/Competent Authority with whom the manufacturer has registered the device* *Provide evidence of registration of ALL the devices listed in section 2.1* *Reference: MDD 93/42/EEC Article 14*
		CHECK	*The evidence includes:* *The name and address of the Regulatory/Competent Authority* *The name and address of the Manufacturer or EC REP & ALL the devices listed in section 2.1* *Free Sales Certificate issued by the Regulatory/Competent Authority or Notified Body are acceptable*
		WARNING	*The evidence of registration must come from the Regulatory/Competent Authority or Notified Body* *A common error is not to include all the 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*
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 the devices listed in section 2.1* *Issued to the Manufacturer of the devices* *Applied Standard listed in section 6.2* *The scope includes the devices listed in section 2.1* *The QMS Certificate is still current & valid*
		WARNING	*The QMS Certificate Scope must cover the 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*
6.6	If the device is a Class I medical device or a	*DO*	*Note: If the device is NOT Class I or General IVD leave sections 6.6 & 6.7 blank.*

No	SFDA Question	*DO* *CHECK* *WARNING*	*Task*
	General IVD, and a QMS is operated but not required by EU directives, is the QMS regularly audited by a an independent organisation? • Yes • No		*Select one option*
		CHECK	*The device is a Class I medical device, or General IVD medical device*
6.7	- If YES, indicate the name of the other organisation and provide a copy of the most recent QMS certificate issued by the independent organisation.	*DO*	*Note: If the device is NOT Class I or General IVD leave this section blank.* *Insert the name of the independent QMS organisation* *Insert a copy of the most recent QMS certificates.*
		CHECK	*The QMS Certificates are:* *QMS Certificate related to the devices listed in section 2.1* *Issued to the Manufacturer of the devices* *Applied Standard listed in section 6.2* *The scope includes the devices listed in section 2.1* *The QMS Certificate is still current & valid*
		WARNING	*The QMS Certificate Scope must cover the devices listed in section 2.1.* *The QMS Certificate must be current & valid*

7. Other National Provisions (KSA)

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	*DO*	*Complete the attestation using the template provided* *The attestation must be printed on the* ***Manufacturers Letterhead*** *GHTF Regulation:* *Devices: as listed in section 2.1* *Manufacturer name & address* *Signed:* *Job Title:* *Dated:*

No	SFDA Question	*DO* *CHECK* *WARNING*	*Task*
	Template provided)		
		CHECK	*Only Europe has been selected as the GHTF Regulation.* *Only the devices in section 2.1 have been listed.* *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.* *List only the devices listed in section 2.1*
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*
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:* *Signed:* *Job Title:* *Dated:* *AR ID Number:*
		CHECK	*The correct application number has been provided.* *The name & address of the AR or LM has been provided* *And the attestation signed, job title and dated*

-END-