Kingdom of Saudi Arabia
Saudi Food & Drug Authority

المملكة العربية السعودية
الهيئة العامة للغذاء والدواء

GUIDANCE FOR COMPLETING SFDA MDMA APPLICATION FORM

EUROPEAN JURISDICTION (EU)

Medical Device Sector

Registration & Licenses Department

Revision: 20/06/2017

V 2.3

Contents

Section 1. Manufacturer (EU)

No	SFDA Question	Do Check Warning	Task
1.1	Manufacturer	Do	• Select the name of the manufacturer from the drop list
1.2	Legal Manufacturer	Do	• Select the name of the **Legal manufacturer.**
		Check	• The name and address of the devices' manufacturer in this application must concur with sections: 2.1.10 Labeling 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 attested letter from the manufacturer explaining that there are two addresses – insert the letter in 2.1.10
1.3	Medical Device Category	Do	• Use SFDA Drop-down list of 17 Categories

Section 2. General info. (EU)

<table>
<tr><th>No</th><th>SFDA Question</th><th>Do
Check
Warning</th><th>Task</th></tr>
<tr><td rowspan="2">2.1</td><td rowspan="2">Details of the medical devices applying for marketing authorization</td><td>Do</td><td>• Insert the list of devices in the application; make sure NOT to list the MODELS separately as different devices.

• For IVD, List the kit as a single item in section 2.1 for labels & IFU, all the labels of the reagent in the kit must be provided.</td></tr>
<tr><td>Check</td><td>• If the application contains multiple products then check that the listed products are meeting the bundling criteria. Refer to SFDA bundling rules in MDS-G7:
(http://www.sfda.gov.sa/en/medicaldevices/regulations/DocLib/MDS-G7.pdf)
• Cross check the list of the devices against:
Labels (2.1.10)
IFU (2.1.11)

• If the device has multiple models, for example male urinary catheters of different sizes, the applicant should include these in one line:
<table>
<tr><th>Product description</th><th>Intended Purpose</th><th>Trade/Brand Name</th><th>Model Number</th></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 rowspan="2">2.1.1</td><td rowspan="2">Product Brief Description (This field will appear on the MDMA printout)</td><td>Do</td><td>• Insert the product brief description.
• <u>Note</u>: The product description will be printed on the MDMA license issued by the SFDA.</td></tr>
<tr><td>Check</td><td>• The product description must be precise and informative (Maximum of 100 Characters including spaces).
• The description must be in English only, no commas (acceptable if it makes sense “part of the sentence” e.g.: infant, pediatric & adult ventilator), clear & accurate.
• Make sure there is no spelling errors.</td></tr>
</table>

		Warning	• "Catheter, Urinary" will be rejected whereas "Urinary Catheter" is acceptable. • Do **NOT** include Brand Names or Company Names **UNLESS** the brand name is descriptive (Describing the product).
2.1.2	**Intended Purpose of the medical device type**	**Do**	• Insert the intended purpose.
		Check	• Typically this is an extract from IFU
2.1.3	**Product Trade/Brand Name.**	**Do**	• Insert the product Trade/Brand name as it appears on the label. • **Note**: The product Trade/Brand Name will be printed on the issued MDMA License.
		Check	• Check it concurs with the product trade/brand name as it appears on the product actual label.
		Warning	• The combination of the Product Description and Trade/Brand Name must be unique for every device listed in the application
2.1.4	**Model Name/Number**	**Do**	• Insert the model name/number as it appears on the label
		Check	• If more than one model number listed in the specified section, these models should only differ in color, size, weight, dimensions or shape.
		Warning	• If the product has model/ref number, the brand name must not be repeated in section 2.1
2.1.5	**Manufacturer's Device Identifier Number**	**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 label.

<table>
<tr><td rowspan="2">2.1.6</td><td rowspan="2">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 the labeling <u>for traceability purposes</u></td></tr>
<tr><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 rowspan="2">2.1.10</td><td rowspan="2">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 93/42/EEC and national provisions OR IVDD 98/79/EEC for IVD.</td></tr>
<tr><td>Check</td><td>• Check that labels provided for <u>ALL</u> the devices listed in section 2.1, including each of the models numbers/REF/Part No. /etc.

• When the device has range (e.g. sizes) then a representative label is acceptable 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></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 legal Manufacturer and must be signed with name, job tittle & date. • The labels must contain: 1- Device Trade name (See 2.1.3) 2- Device model number (See 2.1.4) 3- Device ID Number (REF) (See 2.1.5) 4- Legal Manufacturers Name & Address (See 1.1 & 1.2) 5- CE Mark 6- Notified Body (NB) number (Except: 'Medical devices class I non Measure and non sterile' , ' general IVD ' & Procedure Pack article 12 non measuring and non sterile') 7- EU Rep: Name & address "On the sales packaging (Label, outer packaging or IFU). • Labels May contain: 1- LOT or Serial Number 2- Power Supply – if applicable 3- Storage Temperature 4- Expiry Date 5- Date of manufacture 6- Sterile & method – if applicable 7- Single use – if applicable 8- The term "Made in …." With the country of origin 9- IVD – if applicable 10- IVD Self test – if applicable 11- Rx only – if applicable • **Note: if the device is for professional use only:** It is acceptable if the label provided in English only Reference: SFDA MDS-IR6 Article 9 (C) • **Note: If the device is for home use / Self Test (IVD)** The label provided for each product must be written in both English & Arabic languages. Reference: SFDA MDS-IR6 Article 9 (C)
		Warning	• Common error is wrong or missing label. • Tables, example (NOT Acceptable) Trade Name | REF (Product ID Number) Medical Device | 1234 1236 etc

			The applicant has NOT provided link between the product ID numbers and the product sizes/dimensions.
2.1.11	**Provide Instructions For Use "IFU"**	**DO**	Attach the IFU for ALL devices listed in section 2.1 and it comply with TGA
		Check	• IFU cover ALL the devices Trade/Brand Names listed in section 2.1 • Check that legal Manufacturers name & address are printed on the IFU and it concurs with sections 1.1 & 1.2 • Check it contains Electrical rating –if applicable-. • **Note: if the device is for professional use only** It is acceptable if the label provided in English only Reference: SFDA MDS-IR6 Article 9 (C) • **Note: If the device is for home use / Self Test (IVD)** The label provided for each product must be written in both English & Arabic languages. Reference: SFDA MDS-IR6 Article 9 (C) • Check it contains any WARNING &/or Precautions to take. • Device's models & IDs (must match with 2.1 – if mentioned). If IFU does not cover all models or IDs or Doesn't match with sections 2.1.4 & 2.1.5, a justification is required. • Storage Temperature: Min & Max (Where required) • Sterility Method (Where required) • Single use: (Where required) • Power requirement if applicable (60 Hz Supply at nominal values or either 230 or 400 Volts) • **NOTE: IF IT IS NOT RELEVANT TO HAVE AN IFU FOR THE PRODUCT, THEN THE APPLICANT MUST PROVIDE A JUSTIFICATIOJN FROM THE MANUFACTURER & MUST BE SIGNED, JOB TITTLE & DATED.**

		Warning	• A common error is a wrong or missing information OR missing IFU with no justification
2.1.12	**List of Accessory**	**DO**	• List the accessory for the device (If applicable)
		Check	• Accessory 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 as 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.**	**DO**	• Make selections as appropriate. • Minimumly, AUSTRALIA (AU) must be selected because this is a AU submission.
2.3	**Statement of Power Supply requirements for KSA Market**	**DO**	• If the device/accessory is connected to an a/c power supply, complete the statement Template provided (**It must be printed on the Manufacturer's Letterhead)** • The statement will confirm the medical device 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. (**The statement must be signed, job tittle & dated from the manufacturer**) • If it is **NOT** applicable select the (N/A) box move to the next section.
		Check	• The statement is signed, job tittle & dated from the manufacturer on its letterhead
		Warning	• Do **NOT** alter wording of the SFDA template
2.4	**Statement for KSA Environmental Factors**	**DO**	• Complete the statement template provided printed on Manufacturers letterhead and make sure it is signed, job title & dated.
		Check	• The statement is signed, job tittle & dated from the manufacturer on its letterhead
		Warning	• Do **NOT** alter wording of the SFDA template
2.5	**Statement to correctly stored, transported, installed, maintained &**	**DO**	• Provide a copy of the manufacturer's instructions to ensure that the medical devices 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.

	disposed of medical devices		• 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, also, list devices and accessories Trade/Brand Name in this application (See 2.1) or the application number.
2.6	**Manufacturers advertising & marketing material intended for use in KSA**	**DO**	• Provide a copy of the manufacturer's advertising and marketing material intended for use in the KSA, if **NOT AVAILABLE** provide an explanation and the date when such material will become available, if **NOT REQUIRED** provide a justification. • **Note:** It is acceptable to provide marketing materials that includes more devices than the listed in 2.1, however, the sections of the marketing material that includes the listed products should be **HIGHLITGHED** • **Note:** A product catalogue (Soft copy 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 should contain the manufacturer name • **Note:** It is NOT necessary to have the address of the Manufacturer on the Marketing literature. • It must contains the document control reference number • **Note: if the device is for professional use only** It is acceptable if the marketing material provided in English only Reference: SFDA MDS-IR6 Article 9 (F) • **Note: If the device is for home use / Self Test (IVD)** The Marketing material provided must be written in both English & Arabic languages. 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 • A common error when the Marketing literature includes more devices than the listed in section 2.1 and the relevant devices sections is **NOT** Highlighted. • Marketing literature is **NOT** acceptable if provided on online-link or website.

Section 3. Jurisdiction. (EU)

No	SFDA Question	Do Check Warning	Task
3.1	Desired Jurisdiction	Do	Ensure **EU** jurisdiction has been selected.

Section 4. Product Categories (EU)

No	SFDA Question	Do Check Warning	Task
4.1	Device Type	Do	Select one correct option: • Medical Device • AIMD • IVD
4.2	Device Classification	Do	Select one correct option: • Medical device: 1- Class I 2- Class IIa 3- Class IIb 4- Class III • IVD: 1- Annex II List A 2- Annex II List B 3- Self Test 4- Others
		Check	The selected Device classification is correct for the devices listed in 2.1, and it must concurs the classification stated in section 5 approvals & Certificates
4.3	Class I (only) Sterile Device	Do	• Select the ' **YES** ' if the device is sterile.
4.4	Class I (only) Measuring Device	Do	• Select the ' **YES** ' if the device has Measuring function.


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Section 5. Product Verification (EU)

No	SFDA Question	Do Check Warning	Task
5.1	Indicate the Annex(es)	Do	• Select the applicable Annex(es) from the EU directive applied to the device to establish conformity to EU regulations.
5.2	Name & reference number of the Notified Body	DO	• Provide the name and reference number of the Notified Body responsible for issuing the certificates, decisions or reports required by the conformity assessment Annex(s) referred to above, if any.
5.3	A copy of the current certificates as required by the indicated conformity assessment Annex.	DO	• For Medical Devices Class I non-sterile & non-Measuring devices or general IVD or Procedure Pack article 12 non-Sterile or non Measuring, leave this section blank & select both (N/A) boxes. These classes of devices do not require the involvement of a Notified Body. • For all other devices: 1- Insert 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 year old, a justification* is required from the notified body to confirm the provided audit report is the most recent one. 4- The report must be in English language (Translation must be issued and attested by the notified body OR an independent translator). 5- The report scope must include the EC directive MDD/93/42EEC 6- The report must be of the legal manufacturer. 7- The report must be complete. 8- The report must be less than 1 year old. 9- The report must be signed by the auditor. 10- The report must be recommend continuation of the certification CORRECTIVE ACTIONS – Please note that 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 (NB) that the NB are satisfied with the

			corrective actions and recommends continuation of certification. • For List A IVD: 1- Insert a recent batch release report covering each List A IVD device listed in section 2.1, The SFDA will require confirmation from the NB that the batch release report is acceptable. • **Note**: the MDMA License issued by SFDA will expire: - **Class I devices** – 3 Years - **Class IIa & Class IIb** – EC certificate expiry date - **Class IIII / AIMD / List A IVD / Self Test IVD** – EC Certificates expiry, whichever is earliest. • **Reference:** SFDA Announcement 12/10/MDS-AN003
5.4	**Provide copy of the manufacturer current EC Declaration of conformity DoC**	**DO**	• Provide the current DoC issued by the manufacturer for at least **ALL** the devices listed in section 2.1 &make sure it is: - signed, job tittle & dated from the manufacturer on its letterhead • The DoC should contain: 1- Device trade/brand name & Model numbers 2- Device Classification 3- Notified body name and ID number (if applicable) 4- EC certificate number (if applicable) 5- Date CE mark was applied (if mentioned) 6- EC-REP name & address (If mentioned) 7- Route to compliance Directive & Annex 8- Standard applied (optional) 9- Manufacturer name & address 10- Signed, dated & Job tittle (appropriate member of the Manufacturer) • **References:** - 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
5.5	**Indicate whether the device design has changed**	**Do**	• 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, Select correct answer.
5.6	**For Medical Device Class I , PP article 12 or General IVD (ONLY)**		• Provide Evidence of registration that covers all list devices in section 2.1

Section 6. Manufacturer's QS Status (EU)

No	SFDA Question	Do Check Warning	Task
6.1	Indicate whether the manufacturer of the medical device operates an established quality management system (QMS) that complies with the required conformity assessment procedures	Do	• Select the correct answer.
6.2	If YES, indicate the QMS standard used	Do	• Type the standard used for QMS (Example: ISO 13485)
6.3	the current quality management approvals/certificates held by the manufacturer	Do	• Provide the current Qaulity Management Approval/Certificate held by the manufacturer, which relates to the listed products in section 2.1. • Make sure it is valid.
6.4	Description of the medical devices covered by the QMS	Do	• Write correct description of the medical device/s covered by the QMS provided.
6.5	Indicate the procedure(s) that are included within the Manufacturer's QMS.	Do	• Select the correct procedure and make sure it concur the QMS Provided.

Section 7. Other National Provisions (EU)

No	SFDA Question	Do Check Warning	Task
7.1	Manufacturer Declaration	Do	• Complete the attestation using the SFDA template provided • It must be printed on manufacturers Letterhead • Select **EU** for European based application • The attestation letter must be signed, name, job tittle and dated
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 the technical information to support this attestation.
		Check	The **FULL** Postal address must be provided (Building, number, road, city, postal code, state, country)
7.3	Authorized Representative (AR) Declaration	Do	• Complete the attestation using the SFDA template provided • It must be printed on **AR** / Local Manufacturers (**LM**) Letterhead • Write the correct application number • The attestation letter must be signed with name, job tittle and dated in English and it must match the MDNR information (Arabic & English is Acceptable)