MDS – G11

Guidance on Manufacturing Paths of Medical Devices

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Introduction

Purpose

The purpose of this document is to clarify the manufacturing paths for medical devices within the KSA (including the transfer and localization of their technology) and the associated marketing authorization procedures, as well as addressing requirements for circulation, and import for manufacturing purposes, and obtaining a certificate of free sale for export.

Scope

This document applies to manufacturers of medical devices who perform design and manufacturing (including refurbishing, assembling, packaging, labeling, and placing identifying information) within the KSA.

Background

SFDA has issued this document:

- in reference to the 'Law of Medical Devices' issued by the Royal Decree No. (M/54) dated 6/7/1442 H, and it Implementing Regulation issued by Saudi Food and Drug Authority Board of Directors decree No. (3-29-1443) dated 19/2/1443H.
- in support of the following "National Strategy for Industry" initiatives:
    - Providing technical and commercial support to manufacturers of medical devices.
    - Providing supporting for local supply chain development to enhance localization and ability for complying with regulations.

Requirements

General	1	Manufacturer and medical devices are subject to the provisions of the "Law of Medical Devices" and its Implementing Regulation.
Manufacturing	2	For manufacturing medical devices, the manufacturer shall obtain a medical device manufacturer license, see (MDS-REQ9). Note: One of the license requirements is obtaining a QMS certificate in accordance with ISO 13485:2016, or the latest edition if adopted by the SFDA, from one of SFDA-accredited CABs, see (MDS-REQ9) and (MDS-REQ10).
Manufacturing Paths and MDMA	3	For the circulation of medical devices, the MDMA certificate shall be obtained, see (MDS-REQ1) , and see the manufacturing paths in Annex (1). Notes: – The SFDA grants the MDMA certificate in the name of the manufacturer. – MDMA Requirements are harmonized with international regulations. – The SFDA shall be notified of any significant or non-significant changes to the information provided for the purpose of obtaining MDMA, in accordance with the Guidance on significant and non-Significant changes (MDS-G12). – Devices intended for clinical investigations, research, education, demonstration, training, custom-made purposes, or use in national emergency are exempted from the MDMA (see MDS-REQ5).
Importintion	4	For importing semi-finished medical devices for the purpose of manufacturing them within the KSA and subsequently obtaining the MDMA (after manufacturing), an import permit shall be obtained, see (MDS-REQ5).
Free Sale Certificate	5	For obtaining a Free Sale Certificate for the manufacturer , the application may be submitted in accordance with the requirements specified in (MDS-REQ5). Note: The following are among the requirements for obtaining the certificate – MDMA, see Section (3) above. – Manufacturer License , see Section (2) above.

Technical Support	6	The SFDA provides technical support to manufacturers, free of charge, to clarify the regulatory and technical requirements for manufacturer licensing and obtaining MDMA. The support can be obtained via: – Calling SFDA call center (19999). – Sending an e-mail to the "product registration support section" at md.rs@sfda.gov.sa. – Meeting with SFDA technical team. – Attending relevant workshops.

Annexes

Annex (1): Manufacturing Paths for Manufacturers within the KSA and MDMA Procedure

Manufacturing Paths / MDMA Procedure	Path 1 (Full Manufacturing)	Path 2 (Manufacturing at the Manufacturer's Sites/Branches)	Path 3 (Contract Manufacturing with Third Parties)
	Performing all processes[1] at a single manufacturer site located within the KSA.	Performing part of the processes[1] at a manufacturer site located within the KSA, while the other part is carried out by another site either inside or outside the KSA.	Performing part of the processes[1] at a manufacturer site located within the KSA, while the other part is carried out by an independent manufacturer located outside the KSA, under a contract between the two manufacturers. Additionally, the manufacturer located within the KSA sources one of the product components from an independent manufacturer/supplier located outside the KSA.
The manufacturer responsible for submitting the MDMA application	It is the manufacturer itself.	It is the manufacturer that places the product for use under its name and is legally responsible for it. Note: If the manufacturer responsible for submitting the MDMA application is located outside the KSA, refer to Note (2)	It is the manufacturer that places the product for use under its name and is legally responsible for it. Note: If the manufacturer responsible for submitting the MDMA application is located outside the KSA, refer to Note (2)

Manufacturers' QMS certificate	The certificate shall be submitted. Note: The certificate shall cover all processes.[1]	A separate certificate shall be submitted for each branch/site of the manufacturer that performed any part of the processes[1], or a single certificate covering all parts of the processes[1] performed by the manufacturer and its relevant branches/site. Note: The certificate shall cover the processes[1] carried out by each manufacturer.	An independent certificate shall be submitted for each manufacturer, along with a quality assurance agreement between the contracting manufacturers. Note: The certificate shall cover the processes[1] carried out by each manufacturer.
Product Labelling	It shall bear the name and address of the manufacturer responsible for submitting the application (legal manufacturer), along with the symbol next to it.[2]	It shall bear the name and address of the manufacturer responsible for submitting the application (legal manufacturer), along with the symbol.[2] It is permissible to add the branch/site address, as well as the process[1] performed, such as "Assembled in [manufacturer's name]".	It shall bear the name and address of the manufacturer responsible for submitting the application (legal manufacturer), along with the symbol.[2] It is permissible to add the name and address of another manufacturer.
Technical Documentations	All technical documentation of the product related to all processes[1] shall be submitted.		
Notes	1. If all manufacturing processes are conducted outside the KSA (with no process taking place within the KSA), and the product is imported in its final form, the manufacturing pathways described in this document do not apply. Only one of the following two cases shall apply: a) If the product will be placed for use under the name of the importing establishment, which holds legal responsibility: – This establishment is considered the manufacturer responsible for submitting the MDMA application (legal manufacturer), and shall provide all relevant details and technical documentation showing the design and manufacturing processes, along with the		

	agreements signed between both parties (including the quality assurance agreement). − The labelling shall include the name and address of this establishment (legal manufacturer), along with the symbol.[2] − The labelling shall state the following: • The phrase "Manufacturer for", and the phrase "Manufactured by" can also be stated. • The country of manufacture. b) If the product will not be placed for use under the name of the importing establishment (e.g., when an establishment that does not carry out any of the manufacturing processes agreement with a manufacturer — for whom it is not legally responsible — to label the product as "Manufactured for [name of the establishment]"): − This establishment is not considered a manufacturer. − The technical documentation shall be submitted by the overseas manufacturer or its AR. − The labelling shall include the name and address of the legal manufacturer, along with the symbol.[2] 2. If the manufacturer responsible for submitting the application (legal manufacturer) is located outside the KSA, an AR shall be appointed. The manufacturer may choose one of the following options: a) Submit the application directly (by creating an overseas manufacturer account in the GHAD system, and the AR will not have access to the product's technical documentation). b) Granting its AR the authority to submit the application on its behalf.

[1] Product design and manufacturing processes (manufacturing includes: assembling, packaging, refurbishing and labelling)

[2] The symbol is used where appropriate and in accordance with the standard "Medical devices — Symbols to be used with information to be supplied by the manufactur— Part 1: General requirements (SFDA.MD/ISO 15223-1)".

Annex (2): Definitions & Abbreviations

KSA	Kingdom of Saudi Arabia
SFDA	Saudi Food and Drug Authority
Law	Law of Medical Devices
CABs	Conformity Assessment Bodies
Medical Device	Any instrument, apparatus, implement, implant device, in vitro reagent or calibrator, software, or material used for operating medical devices, or any other similar or related article, intended to be used alone or in combination with other devices for diagnosis, prevention, monitoring, controlling, treatment, or alleviation of disease or injury, or for compensation for an injury; investigation, replacement, modification, or support of the anatomy or of a physiological process; supporting or sustaining life; controlling or assisting conception; sterilization of medical devices ; providing information for medical or personal purposes by means of in vitro examination of specimens derived from the human body; and does not achieve its primary intended action by pharmacological, immunological or metabolic means, but which may be assisted in its intended function by such means
Medical Supply	A medical substance or product used in diagnosis, treatment, prosthetics, or orthotics; or in disability cases or other medical uses for humans, including medical gases.
Manufacturer	Any national or foreign establishment the purposes of which include designing or manufacturing medical devices for use under its name within the Kingdom or abroad. Manufacturing shall include refurbishing, assembling, packaging, and labelling.
Authorized Representative (AR)	A legal person based in the Kingdom who has written authorization from a manufacturer located outside the Kingdom to represent it in the Kingdom with regard to the implementation of this Law and its Regulations.
Distributer	An establishment in the supply chain that supplies the medical device to another distributor or end user.
Circulation of Medical Devices	The provision of medical devices at no cost or for a fee, whether for distribution or use.
Marketing Authorization (MDMA)	A document issued by the SFDA permitting the circulation of a medical device in the market.
Quality Management System (QMS)	A system approved by the SFDA to verify the quality, effectiveness, and safety of a medical device in accordance with the latest edition of the Technical Standard (ISO 13485) or its equivalent, as provided in the Regulations.

Identifying Information (Labeling)	Any statement, information, or illustration printed on a medical device, including identifying information, technical description, method of use, and manner of storage and transportation.
Technical Documentation	Technical and scientific documentation and information related to the medical device and Manufacturer, including documented and approved procedures, which prove that the medical device conforms to the safety, efficacy, and quality requirements specified in the Law and its Regulation.
Qality Assurance Agreement	Document between the manufacturer submitting the application (the Legal Manufacturer) and the contracted manufacturer, which obligates the contracted manufacturer to manufacture in accordance with the specifications and regulatory requirements previously defined by the Legal Manufacturer.

Annex (3): List of Changes in the Previous Version

Number and Date of the Previous Version	Changes Description
1.0 22/3/2023	- Rearranging the "Requirements". - Adding notes in paragraph (3): Manufacturing pathways and MDMA. - Adding definitions (Quality Assurance Agreement, Full Manufacturing, Contract Manufacturing). - Changing to the pathways in Annex (1).