الهيئة العامة للغذاء والدواء
Saudi Food & Drug Authority

MDS – G011

Guidance on Manufacturing Paths of Medical Devices

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Introduction

Purpose

The purpose of this document is to clarify paths of manufacturing medical devices locally (including the transfer of its technology and its settlement in the KSA), its circulation, distribution within the KSA and exportation, in addition to guide manufacturers to the SFDA requirements published on its website.

Scope

This document applies to local manufacturers of medical devices.

Background

SFDA has issued this document in reference to the "Law of Medical Devices" and it Implementing regulation, and 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.
Requirements of Manufacturing	2	For local manufacturing of medical devices, manufacturer shall obtain a Medical Devices Manufacturer License (see MDS-REQ9), which requires to obtain a Quality Management System certificate according to (SFDA.MD/GSO ISO 13485:2017) or the latest edition if it has been adopted by the SFDA from one of conformity assessments bodies and the Quality Management System (see MDS-REQ10).
Requirements of Circulation and Distribution	3	For the circulation and distribution of medical devices within the KSA, the following shall be considered: – Medical devices shall obtain MDMA by the manufacturer, see section (4) below. – Establishment (manufacturer or any other establishment) that wishes to distribute shall obtain a Medical Devices Distributor License (see MDS-REQ9). Notes: – The SFDA provide the MDMA certificate for the manufacturer, including its name. – Requirements for obtaining a MDMA are harmonized with international regulations, which facilitates its circulation inside and outside the KSA. – The following medical devices are exempt from the MDMA: intended for the purpose of clinical studies, research, education, demonstration, training, custom-made medical devices, or used for public emergency.
Paths of Manufacturing	4	For obtaining MDMA, the application shall be submitted in accordance with requirements specified in (MDS-REQ1) and according to one of the manufacturing cases/paths (Full, Partial or Contracted) specified in Annex (1).
Innovative Medical Devices	5	Innovative medical devices are exempt from certain requirement of MDMA (See MDS-G2)

Requirements of Free Sale Certificate	6	"Certificate of Free Sale" can be obtained (see MDS-REQ5), which requires obtaining MDMA (see MDS-REQ1), and a Manufacturer License (see MDS-REQ9).
Requirements of Importing for the Purpose of Local Manufacturing	7	Local manufacturer has the right to import medical devices in their semi-finished form for the purpose of manufacturing them locally (see MDS-REQ5), provided that it subsequently obtain MDMA after its manufacture (see MDS-REQ1)
Technical Support	8	The SFDA provides technical support to manufacturers, free of charge, to clarify the regulatory and technical requirements for manufacturer licensing and medical devices marketing authorization. The support can be obtained via: – Calling the unified number of SFDA (19999). – Sending an e-mail to "product registration support section" md.rs@sfda.gov.sa. – Meeting with SFDA technical team. – Attending relevant workshops.

Annexes

Annex (1): Manufacturing Paths and Marketing Authorization

The following table clarifies relationship of the manufacturing path to the MDMA procedures (MDS-REQ1), where the MDMA application is submitted according to one of the following manufacturing cases/paths:

MDMA	Manufacturing Paths			
	First Path Complete Manufacturing It means: the local manufacturer that wants to sell the product in its name, perform all stages of manufacturing	Second Path Partial Manufacturing It means: the local manufacturer that wants to sell the product in its name, perform one or more of the manufacturing stages (such as sterilization, packaging and/or assembly...etc.)	Third Path Contract Manufacturing (Full or Partial) It means: the local manufacturer perform all or part of the manufacturing stages on behalf of another legal manufacturer (whether the product has MDMA or not)	Forth Path Contract Purchase It means: a local manufacturer (or any other establishment) that buys a final product from the original manufacturer (the original manufacturer has done all the manufacturing stages and put the name of the local manufacturer on the final product) and sells it in the KSA in local manufacturer name
1. Legal Manufacturer?	Local manufacturer	Local manufacturer	The legal manufacturer who the local manufacturer manufactures for. Note: local manufacturer considers one of manufacturing sites of the legal manufacturer	Local manufacturer

2. Responsible for submitting the MDMA?	Local manufacturer	Local manufacturer	The legal manufacturer Note: The AR of manufacturer residing outside the KSA can provide the MDMA application on behalf of the manufacturer	A. The local manufacturer, in case of he obtained all technical documentations from the original manufacturer. B. The original manufacturer, in case of he does not allow the local manufacturer to access all technical documentations, with the providing an agreement between them.
3. Technical Documentations?	The local manufacturer shall have all the technical documentations of the product and submit them within the application	The local manufacturer shall have the technical documentation of the product, including agreements and technical documentation that cover all stages of manufacturing (including the stages of manufacturing that were previously completed by the original manufacturer)	A. In the event that the product has previously obtained MDMA: Technical documentations that prove that the product to be manufactured is the same as the previously marketed product shall be submitted, in addition to the agreements related to manufacturing stages. B. In the event that the product does not have a MDMA: All necessary technical documentations shall be submitted, in	A. In case of the original manufacturer allows the local manufacturer to access the product's technical documentations, the legal manufacturer (the local manufacturer) shall provide all the product's technical documentations. The name of original manufacturer does not have to be on

			addition to the agreements related to manufacturing stages	the product's labelling, but his information shall be part of the information submitted for the purpose of obtaining MDMA. B. In case of the original manufacturer does not allow the local manufacturer to access the product's technical documentations, the original manufacturer can provide the technical documentations instead of the legal manufacturer (the local manufacturer).
4. Manufacturer's QMS certificate?	Local manufacturer shall obtain the QMS certificate	The local manufacturer shall obtain a QMS certificate, and it's scope shall cover all stages of manufacturing that it performs, and shall provide the QMS certificate with relevant agreements with the original manufacturer	The legal manufacturer shall have a QMS certificate, and if it manufactures the relevant product in a local manufacturer, the certificate shall include the name of the local manufacturer or a quality agreement between the local manufacturer and the legal manufacturer.	Both manufacturers shall have the QMS certificate

SFDA

Annex (2): Definitions & Abbreviations

KSA	Kingdom of Saudi Arabia
SFDA	Saudi Food and Drug Authority
Law	Law of Medical Devices
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	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.