MDS – G013

Guidance on Medical Devices Samples Collection

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Introduction

Purpose

The purpose of this document is to clarify the procedures of medical devices samples collection for laboratory testing in order to ensure their quality, safety, and effectiveness, and their conformity with the standards approved by the SFDA.

Scope

This document applies to:

- Manufacturers.
- Authorized Representatives.
- Importers and Distributors (including Partial sale establishments).
- Medical Devices Samples intended to be tested in SFDA labs or accredited lab, in the following situations:
  - Incoming shipments through customs ports.
  - Inspection.
  - Investigation based on incident report, complaint or suspected cases (e.g. misleading medical claims, sterilization or labeling malfunctioning, inappropriate environment conditions, commercial adulteration or others).
  - Targeted medical devices in the SFDA annual monitoring plan.

Background

The SFDA has issued this document in reference to:

- (Article 3) and (Article 5, “Executive duties” item no. 4) of the "Saudi Food and Drug Authority Law" issued by Royal Decree No. (M/6) dated 25/1/1428 AH which assign to the SFDA the testing of products fall under its jurisdiction in its laboratories or other laboratories chosen thereby, and to undertake testing medical devices, glasses, contact lenses and electronic products that have an effect on human health, in order to ensure their quality, safety, effectiveness and compliance with SFDA technical regulations, and to undertake testing and analyzing of in vitro diagnostics to ensure their quality, safety, effectiveness and compliance with manufacturer specifications.

- Item (B.) of (Article 33) of the "Medical Devices Law" issued by the Royal Decree No. (M/54) dated 6/7/1442 AH stipulated that “Taking samples for analysis”.

- (Article 11/10) and (Article 39/1 item 4.) of the "Implementing Regulation of Medical Devices Law" issued by Saudi Food and Drug Authority Board of Directors decree No. (3-29-1443) dated 19/2/1443 AH.

Procedures of Samples Collection

- The SFDA specifies and collect samples from targeted medical devices in accordance to related international standards, practices and procedures (e.g. the international standard ISO 2859-1).
- The SFDA provides the establishment with a notice of samples collection.
- Establishment wishing to retrieve their not affected samples shall contact SFDA medical devices lab within (30 days) from the date of the issuance of testing results, and submit the following documents:
    - Saudi ID.
    - Authorization letter from the establishment authorized person to retrieve the samples.
    - Copy of the shipment clearance letter, if applicable.
    - Copy of the notice of samples collection.
- The documents submitted through:
    - Email (mdlab@sfda.gov.sa).
    - Handling at SFDA medical devices lab on the following address: SFDA Complex Laboratories, Prince Abdulaziz Bin Abdullah Bin Turki St, Riyadh 1st industrial city, Riyadh.

Final Provisions

1. The SFDA may take preventive and precautionary measures if given cause to believe that there is a harm, misleading claims or an impact on the safety and efficacy of medical devices, including collecting a sample to be examined in a laboratory and conducting the necessary tests, at the expense of the establishment. The establishment shall not act on the remaining quantity in case SFDA request that.

2. The SFDA may collect random samples from incoming shipments through customs ports to ensure their safety and effectiveness, without bearing any costs of such samples or the costs of examining them in laboratories.

3. Whoever commits any violation shall be penalized according to the "Table of the Classifications of Violations and Penalties According to the Medical Devices Law and its Implementing Regulation".

Annexes

Annex (1): Definitions & Abbreviations

SFDA	Saudi Food and Drug Authority
Medical Device	Any instrument, apparatus, applied devices, implant devices, in vitro diagnostic reagent or calibrator, software, or material used for operating medical devices, 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 a physiological process; supporting or sustaining life; controlling or assisting conception; sterilization of medical devices; providing information for medical or diagnostic 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, in return it may be assisted in its intended function by such means.
Adulterated Medical Devices	Medical devices that have had their identity or source intentionally changed with the intent of deception. Medical devices are considered adulterated if their contents have been changed in a way that adversely affects their safety and security, or if they are packaged in counterfeit packages.
Establishment	A legal entity involved in an activity related to medical devices.
Manufacturer	Any national or foreign establishment whose purposes include designing or manufacturing medical devices to offer them for use in its own name, whether inside or outside the Kingdom. Manufacturing includes: • refurbishing; • assembling; • packaging; • packaging; and • labelling.
Authorized Representative	A legal person based in the Kingdom who is authorized, in writing, by a Manufacturer located outside the Kingdom to represent it within the Kingdom with regard to the implementation of the "Medical Devices Law and its Regulation".
Importer	An establishment in the supply chain that imports a medical device to the Kingdom.
Distributor	An establishment in the supply chain which provides a medical device to another distributor or its end user.
Standards	Non-mandatory documents endorsed by the SFDA which include: • rules and/or guidelines;

	• characteristics of medical devices; and/or • related production processes and methods, including: - terminology; - symbols; - packaging; and - labeling requirements.
Labeling	Any statement or information drawn or illustrated / written or printed on the medical device, including: • Name of the device; • Code / lot or serial number; • technical description; • method of use; and / or • manner of storage and transportation.
Complaint	Any form of written or oral communication regarding deficiencies related to the medical device. These include, but are not limited to: • quality; • efficacy; • efficiency; • usability; • safety or performance; and / or • deficiencies related to maintenance that affect the performance of the medical device.
Inspection	A systematic and documented procedure carried out by the SFDA to verify the establishment and / or the Manufacturer's obligations with regard to the particular conditions and requirements for establishments and medical devices set forth in the Law and its Regulation.
Surveillance	A set of procedures to control the safety, efficacy, quality, and effectiveness of medical devices during their circulation within the Kingdom.
Partial sale establishments	Establishments that carry out the process of selling home-use medical devices to the end user through retail markets such as canters, exhibitions and electronic stores, but are not primarily involved in importing and distributing medical devices.

Annex (2): List of Changes on the Previous Version

Number & Date of the Previous Version	Changes Description
3.0 01/05/2023	• Editorial modifications on the “Purpose”. • Editorial modifications on the “Scope”. • Editorial modifications on the “Background”. • Editorial modifications on the “Procedures of Samples Collection”. • Editorial modifications on the “Final Provisions”. • General Modifications on the “Annex (1) Definitions & Abbreviations”.