MDS – G006

Guidance for Requirements of blood glucose metering devices and strips for home use - Recognized Standards

Version Number: 1.1
Version Date: 14/12/2022

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Introduction

Purpose

The purpose of this guide is to define and clarify the recognized Standards for obtaining Marketing Authorization for blood glucose metering devices and strips for home use.

Scope

This guidance applies to manufacturers and authorized representatives of blood glucose metering devices and strips for home use.

Background

SFDA has issued this guidance according to the following:

- Article 8 of the "Medical Devices Law" issued by the Royal Decree No. (M/54) dated 06/07/1442 H
- Articles (10/2) and (10/28) of the Implementing Regulations of the Medical Devices Law issued by Board Resolution No. (3-29-1443) dated 19/02/1443 H
- Requirements for Medical Device Marketing Authorization (MDS-REQ 1)".

Requirements

General	1	▪ A medical device cannot be circulated in the Kingdom unless it has been scientifically evaluated by the SFDA in accordance with the Requirements for Medical Device Marketing Authorization (MDS-REQ 1) to ensure its safety and effectiveness. ▪ Submission of the necessary documents to prove that the medical device to be marketed complies with the Essential Principles of Safety and Performance which specified in the Requirements for Medical Device Marketing Authorization (MDS-REQ 1), including proof of compliance with relevant Standards. Clause (2) below refers to examples of recognized Standards which can be used as a means of demonstrating compliance with these "Essential Principles of Safety and Performance". Note: All requirements and test methods indicated in the applicable Standards that referred to in the Marketing Authorization application shall be met, and if that is not possible, the SFDA shall be provided with justifications.
Recognized Standards	2	a. In Vitro Diagnostic Medical Devices — Clinical Performance Studies Using Specimens from Human Subjects — Good Study Practice (SFDA.MD/ISO 20916:2021) b. In vitro diagnostic medical devices — Evaluation of stability of in vitro diagnostic reagents (SFDA.MD/ISO 23640:2017) c. In vitro diagnostic test systems. Requirements for blood-glucose monitoring systems for self-testing in managing diabetes mellitus (SFDA.MD/ GSO ISO 15197:2015) d. Clinical laboratory testing and in vitro medical devices — Requirements for in vitro monitoring systems for self-testing of oral anticoagulant therapy (ISO 17593:2022) e. General Requirements For In Vitro Diagnostic Medical Devices for Self-Testing (GSO EN 13532:2021) f. Performance evaluation of in vitro diagnostic medical devices (EN 13612:2002) g. Elimination or reduction of risk of infection related to in vitro diagnostic reagents (EN 13641:2002)
Labeling	3	The labeling must comply with the following: - Requirements for labeling specified in the applicable Standards. - Requirements for labeling and information provided by the manufacturer specified in the Requirements for Medical Device Marketing Authorization (MDS-REQ1).

Annexes

Annex (1): Definitions & Abbreviations

KSA	Kingdom of Saudi Arabia
SFDA	Saudi Food and Drug Authority
Medical Devices	Any instrument, apparatus or implement or implant or in vitro reagent or calibrator or 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 or prevention or monitoring or controlling or 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 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, but which may be assisted in its intended function by such means.
Manufacturer	Any national or foreign establishment the purposes of which include designing or manufacturing medical devices or supplies for use under its name within the Kingdom or abroad. Manufacturing shall include refurbishing, assembling, packaging, and labelling.
Authorized Representative	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.
Marketing Authorization	A document issued by the SFDA permitting the circulation of a medical device or supply in the market.
Standards	Non-mandatory documents approved by the SFDA, including rules, guidelines, specifications of medical devices and supplies, or production processes and methods related thereto as well as terms and symbols, and packaging and labelling requirements.
Labeling	Any statement, information, or illustration printed on a medical device or supply, including identifying information, technical description, method of use, and manner of storage and transportation.