MDS – G46

Guidance on Requirements for Medical Masks - Recognized Standards

Medical Device Sector

Saudi Food and Drug Authority

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This guidance document will be immediately implemented without prior public comment, SFDA will still review all comments received and revise the guidance document as appropriate.

Table of Content

Introduction

Purpose

The purpose of this guidance is to specify and clarify the requirements and recognized standards for obtaining Medical Devices Marketing Authorization (MDMA) of medical masks, in order to place them on the market within the KSA.

Scope

This guidance applies to the following:

- Manufacturers, authorized representatives, importers and distributers
- Surgical/medical and N95 respirator masks used to protect both the patient and the healthcare personnel from the transfer of microorganisms, body fluids and particulate materials.

Background

SFDA/MDS has issued this guidance document in reference to the following:

- Article Three of "The Law of Saudi Food and Drug Authority"
- Requirements specified in "Guidance on Requirements for Medical Device Marketing Authorization (MDS – G5)".

Requirements

General	1	Obtaining Medical Devices Marketing Authorization (MDMA) for medical masks by submitting an electronic application via: https://ghad.sfda.gov.sa/en
	2	Medical masks specified in the "scope" of this document shall comply with requirements specified in "Guidance on Requirements for Medical Device Marketing Authorization (MDS – G5)".
Recognized Standards	3	Manufacturers are expected to follow state-of-the-art standards and guidance as required by SFDA Essential Principles, or evidence of equivalent demonstration of compliance. Compliance with the following standards can

		be used to demonstrate fulfillments of relevant Essential Principles: A. EN 14683:2019 "Medical face masks. Requirements and test methods" B. ASTM F2100 – 11(2018) "Standard specification for performance of materials used in medical face masks" C. GSO ISO 22609:2009 "Clothing for protection against infectious agents - Medical face masks - Test method for resistance against penetration by synthetic blood (fixed volume, horizontally projected)" D. ASTM F2101 – 14 "Standard test method for evaluating the Bacterial Filtration Efficiency (BFE) of medical face mask materials, using a biological aerosol of staphylococcus aureus" E. ASTM F1862/F1862M – 17 "Standard test method for resistance of medical face masks to penetration by synthetic blood (horizontal projection of fixed volume at a known velocity)" F. SFDA.MD/ISO 10993-1:2018 "Biological Evaluation of Medical Devices -- Part 1: Evaluation and testing within a risk management process" G. SFDA.MD/ISO 10993-10:2018 "Biological evaluation of medical devices -- Part 10: Tests for irritation and skin sensitization" H. ISO 11737-1:2018 "Sterilization of medical devices - Microbiological methods - Part 1: Determination of a population of microorganisms on products" I. EN 1041:2008+A1:2013 "Information supplied by the manufacturer of medical devices" J. SFDA.MD/ ISO 15223-1 "Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements"

		K. EN 149:2001+A1:2009 " Respiratory protective devices - Filtering half masks to protect against particles - Requirements, testing, marking "
The Required Tests	4	• The ability of medical masks to resist BFE (bacterial filtration efficiency). • The ability of medical masks to resist PFE (particulate filtration efficiency). • The ability of medical masks to resist fluid penetration. • The ability of medical masks to resist flammability. • Ventilation pressure (pressure differential).
Labeling	5	The labeling of mask shall : – comply with labeling requirement specified in "Guidance on Requirements for Medical Device Marketing Authorization (MDS – G5)", and – include the following information: o Intended use of the mask, by identifying whether it is medical, surgical, N95 mask, etc…. o Indications for use, such as whether the mask is an isolation mask, procedure mask, or dental facemask. o Statement about flammability warning, such as this device may burn when used in the presence of high intensity heat source or flammable gas. o Regular masks shall be labeled as non-medical uses.

Annexes

Annex (1): Definitions & Abbreviations

KSA	Kingdom of Saudi Arabia
SFDA	Saudi Food and Drug Authority
MDS	Medical Devices Sector
Manufacturer	Means any natural or legal person with responsibility for design and manufacture of a medical device with the intention of making it available for use, under his name; whether or not such a medical device is designed and/or manufactured by that person himself or on his behalf by another person.
Authorized Representative (AR)	Means any natural or legal person established within the KSA who has received a written mandate from the manufacturer to act on his behalf for specified tasks including the obligation to represent the manufacturer in its dealings with the SFDA.
Importer	Means any natural or legal person established within the KSA that places a device from a third country on the KSA market.
Distributer	Means any natural or legal person in the supply chain who, on his own behalf, furthers the availability of a medical device to the end user.
Medical Face Mask	A product designed to protect portions of the wearer's face, including the mucous membrane areas of the wearer's nose and mouth, from contact with blood and other body fluids during medical procedures. Examples of medical face masks include surgical masks, procedure masks, isolation masks, and dental masks. (See annex 2 for the classification and the applications of medical masks).
N95 Respirator Mask	Mask fitted to the user's face, forming a seal that provides a physical barrier to fluids, particulate materials, and aerosols.

Annex (2): Classification and Applications of Medical Face Masks

In reference to the recognized standards, Medical Face masks can be divided into Three levels:

- **Level (A): BFE ≥ 95%**

To be used for general medical procedures where there is no risk of blood or body fluid splash.

- **Level (B): BFE ≥ 98% without or with low splash resistance.**

To be used in Emergency, change dressing room, dentistry, and other similar procedures.

- **Level (C): BFE ≥ 98% with high splash resistance.**

To be used in surgical procedures or other procedures with similar requirements.