الهيئة العامة للغذاء والدواء
Saudi Food & Drug Authority

MDS – G46

Guidance on Requirements for Medical Masks and Particulate Respirators – Recognized Standards

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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
- Medical masks (including surgical masks) and particulate respirators.

Except non-medical masks that labeled as "For Non-Medical Use" which are regulated by the Saudi Standards, Metrology and Quality Organization (SASO) and they shall comply with the "Guidance for Non-Medical Masks".

Background

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

- Article Three of “The Law of Saudi Food and Drug Authority” issued by the Royal Decree No.(M/6) issued on 25/1/1428 H
- Requirements specified in “Guidance on Requirements for Listing and Medical Device Marketing Authorization (MDS – G5)”.

Requirements

General	1	Medical masks and particulate respirators shall obtain Medical Devices Marketing Authorization (MDMA), and shall be complied with the requirements specified in "Guidance on Requirements for Listing and Medical Device Marketing Authorization (MDS – G5)", including "Essential Principles of Safety and Performance" specified in the mentioned guidance. Paragraph (2) below is examples of SFDA recognized standards, which may be used, depending on the type of medical masks and particulate respirators as a means of demonstrating compliance with the "Essential Principles of Safety and Performance" Note: All requirements and tests specified in the applied standard(s), mentioned in the submitted MDMA application, shall be met.
Recognized Standards	2	Relevant recognized standards for medical masks and particulate respirators: A. EN 14683:2019+AC: 2019 "Medical face masks Requirements and test methods" B. ASTM F2100 – 19e1 "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 F2299 ASTM F2299/F2299M – 03(2017) "Standard Test Method for Determining the Initial Efficiency of Materials Used in Medical Face Masks to Penetration by Particulates Using Latex Spheres" F. EN 149:2001+A1:2009 "Respiratory protective devices - Filtering half masks to protect against particles - Requirements, testing and marking" G. NFPA 702 "Standard for Classification of the Flammability of Wearing Apparel" H. 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)"

		I. SFDA.MD/ISO 10993-1:2018 "Biological Evaluation of Medical Devices -- Part 1: Evaluation and testing within a risk management process" J. SFDA.MD/ISO 10993-5:2018 "Biological evaluation of medical devices -- Part 5: Tests for in vitro cytotoxicity" K. SFDA.MD/ISO 10993-10:2018 "Biological evaluation of medical devices -- Part 10: Tests for irritation and skin sensitization" L. ISO 11737-1:2018 "Sterilization of medical devices - Microbiological methods - Part 1: Determination of a population of microorganisms on products" M. EN 1041:2008+A1:2013 "Information supplied by the manufacturer of medical devices" N. 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" O. Relevant standard test procedures (STPs) of NIOSH
Labeling	3	Labeling of medical masks and particulate respirators shall be complied with the following: - Labelling requirements specified in the applied standard(s). - Labeling requirements specified in "Guidance on Requirements for Listing and Medical Device Marketing Authorization (MDS – G5)".

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).
Particulate Respirator	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.

Annex (3): Examples for Required Tests

- Required tests for medical mask:
  - Bacterial filtration efficiency (BFE)
  - Breathability (Differential pressure)
  - Splash resistance/Penetration by Synthetic Blood
  - Microbial cleanliness (Bioburden)
  - Biocompatibility
  - Sub-Micron Particulate Filtration
  - Flammability test

- Required tests for particulate respirators:
  - Differential pressure following appropriate NIOSH standard test procedures (STPs):
    - Determination of Exhalation Resistance
    - Determination of Inhalation Resistance
  - Particulate filtration efficiency following appropriate NIOSH standard test procedure (STP):
    - Determination of Particulate Filter Efficiency Level for N95 Series Filters Against Solid Particulates for Non-Powered, Air-Purifying Respirators testing procedure
  - Exhalation valve leakage following appropriate NIOSH standard test procedure (STP):
    - Determination of Exhalation Valve Leakage
  - Biocompatibility
  - Splash resistance/Penetration by Synthetic Blood
  - Practical performance
  - Leakage
  - Flammability
  - Carbon dioxide content of the inhalation air
  - Strength of attachment of exhalation valve housing
  - Breathing Resistance
  - Clogging

Annex (4): List of Changes on the Previous Version

Number & Date of the Previous Version	Changes Description
3.0 17/6/2020	• Changing in the text of "Introduction" • Changing in the text of sections "Requirements" • Adding Annex (3)