MDS – G47

Guidance on Requirements for Ventilators, Ventilator Tubing Connectors, and Ventilator Accessories – Recognized Standards

Medical Device Sector

Saudi Food and Drug Authority (SFDA)

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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.

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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 ventilators, ventilator tubing connectors, and ventilator accessories, in order to place them on the market within the KSA.

Scope

This guidance applies to Manufacturers, authorized representatives, importers, and distributors of ventilators, ventilator tubing connectors, and ventilator accessories.

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	Ventilators, ventilator tubing connectors, and ventilator accessories specified in the "scope" of this document shall comply with requirements specified in "Guidance on Requirements for Medical Device Marketing Authorization (MDS – G5)". 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 applicable following standards can be used to demonstrate fulfillments of relevant Essential Principles:
Collateral IEC 60601 series standards	2	• SFDA.MD/IEC 60601-1:2015 "Medical electrical equipment - Part 1: General requirements for basic safety and essential performance" • SFDA.MD/IEC 60601-1-2:2015 "Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests" • SFDA.MD/IEC 60601-1-6:2015 "Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability" • SFDA.MD/IEC 60601-1-8:2015 "Medical electrical equipment - Part 1-8: General requirements for basic safety and essential performance - Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems" • SFDA.MD/IEC 60601-1-9:2015 "Medical electrical equipment - Part 1-9: General requirements for basic safety

		and essential performance - Collateral Standard: Requirements for environmentally conscious design” • SASO-IEC-60601-1-10:2015 “Medical electrical equipment — Part 1-10: General requirements for basic safety and essential performance — Collateral standard: Requirements for the development of physiologic closed-loop controllers” • SFDA.MD/IEC 60601-1-11:2015 “Medical electrical equipment - Part 1-11: General requirements for basic safety and essential performance - Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment” • SFDA.MD/IEC 60601-1-12:2015 “Medical electrical equipment - Part 1-12: General requirements for basic safety and essential performance - Collateral Standard: Requirements for medical electrical equipment and medical electrical systems intended for use in the emergency medical services environment”
Particular IEC 60601/ISO 80601 series standards	3	• GSO ISO 80601-2-12:2015 “Medical electrical equipment — Part 2-12: Particular requirements for basic safety and essential performance of critical care ventilators” • ISO 80601-2-13:2011 “Medical electrical equipment — Part 2-13: Particular requirements for basic safety and essential performance of an anaesthetic workstation” • GSO ISO 80601-2-55:2015 “Medical electrical equipment — Part 2-55: Particular requirements for the basic safety and essential performance of respiratory gas monitors” • SFDA.MD/ISO 80601-2-70:2017 “Medical electrical equipment — Part 2-70: Particular requirements for basic safety and essential performance of sleep apnoea breathing therapy equipment” • SFDA.MD/ISO 80601-2-72:2017 “Medical electrical equipment — Part 2-72: Particular requirements for basic safety and essential performance of home healthcare environment ventilators for ventilator-dependent patients” • SFDA.MD/ISO 80601-2-74:2018 “Medical electrical equipment — Part 2-74: Particular requirements for basic safety and essential performance of respiratory humidifying equipment” • SFDA.MD/ ISO 80601-2-79:2020 “Medical electrical equipment — Part 2-79: Particular requirements for basic safety and essential performance of ventilatory support equipment for ventilatory impairment” • ISO 80601-2-80:2018 “Medical electrical equipment — Part 2-80: Particular requirements for basic safety and essential performance of ventilatory support equipment for ventilatory insufficiency”
Particular ventilators’ related standards	4	• ISO 10651-3:1997 “Lung ventilators for medical use — Part 3: Particular requirements for emergency and transport ventilators” • GSO ISO 10651-4:2015 “Lung ventilators — Part 4: Particular requirements for operator-powered resuscitators”

		• GSO ISO 10651-5:2015 "Lung ventilators for medical use — Particular requirements for basic safety and essential performance — Part 5: Gas-powered emergency resuscitators" • SFDA.MD/ISO 17510:2017 "Medical devices — Sleep apnoea breathing therapy — Masks and application accessories"
Ventilator tubing connectors, and ventilator accessories	5	• SFDA.MD/ISO 18082:2015 "Anaesthetic and respiratory equipment — Dimensions of non-interchangeable screw-threaded (NIST) low-pressure connectors for medical gases" • SFDA.MD/ISO 5356-1:2015 "Anaesthetic and respiratory equipment — Conical connectors — Part 1: Cones and sockets" • SFDA.MD/ISO 5356-2:2015 "Anaesthetic and respiratory equipment — Conical connectors — Part 2: Screw-threaded weight-bearing connectors" • SFDA.MD/ISO 5361:2018 "Anaesthetic and respiratory equipment — Tracheal tubes and connectors" • SFDA.MD/ISO 5366:2018 "Anaesthetic and respiratory equipment — Tracheostomy tubes and connectors" • SFDA.MD/ISO 5367:2015 "Anaesthetic and respiratory equipment — Breathing sets and connectors" • GSO ISO 5359:2016 "Anaesthetic and respiratory equipment — Low-pressure hose assemblies for use with medical gases" • SFDA.MD/ISO 18190:2017 "Anaesthetic and respiratory equipment — General requirements for airways and related equipment" • ISO 18250-1:2020 "Medical devices — Connectors for reservoir delivery systems for healthcare applications — Part 1: General requirements and common test methods"
Biological evaluation and biocompatibility	6	• SFDA.MD/ISO 10993-1:2018 "Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process" • SFDA.MD/ISO 18562-1:2017 "Biocompatibility evaluation of breathing gas pathways in healthcare applications — Part 1: Evaluation and testing within a risk management process" • SFDA.MD/ISO 18562-2:2017 "Biocompatibility evaluation of breathing gas pathways in healthcare applications — Part 2: Tests for emissions of particulate matter" • SFDA.MD/ISO 18562-3:2017 "Biocompatibility evaluation of breathing gas pathways in healthcare applications — Part 3: Tests for emissions of volatile organic compounds (VOCs)" • SFDA.MD/ISO 18562-4:2018 "Biocompatibility evaluation of breathing gas pathways in healthcare applications — Part 4: Tests for leachables in condensate"
Safety of batteries	7	• SASO-IEC-60086-4:2007 "Primary batteries - Part 4: Safety of lithium batteries" • SASO-IEC-62281:2018 "Safety of primary and secondary lithium cells and batteries during transport"

		• SASO-IEC-62133-1:2017 “Secondary cells and batteries containing alkaline or other non-acid electrolytes - Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications - Part 1: Nickel systems” • SASO-IEC-62133-2:2017 “Secondary cells and batteries containing alkaline or other non-acid electrolytes - Safety requirements for portable sealed secondary lithium cells, and for batteries made from them, for use in portable applications - Part 2: Lithium systems”
Software	8	• SFDA.MD/IEC 62304+AMD 1:2017 “Medical device software - Software life cycle processes”
Usability	9	• SFDA.MD/IEC 62366-1:2018 “Medical devices - Part 1: Application of usability engineering to medical devices”
Risk Management	10	• SFDA.MD/ISO 14971:2017 “Medical devices — Application of risk management to medical devices”
Labeling	11	• SFDA.MD/ISO 15223-1:2017 “Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements” • EN 1041:2008+A1:2013 “Information supplied by the manufacturer of medical devices”

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.
Authorised 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.
Ventilator	Medical device intended to provide artificial ventilation.