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MEDICAL DEVICE GUIDANCE DOCUMENT

MEDICAL FACE MASK AND RESPIRATOR

In lieu of the rise of the emergency situation where the Covid-19 pandemic has occurred, the Medical Device Authority (MDA) has published this guidance document without seeking public comment as per the usual practice. This is to enable the guidance document to be published in the shortest possible period. MDA will not seek public comment prior to implementing a guidance document if the Authority determines that prior public participation is not feasible or appropriate.

Medical Device Authority
MINISTRY OF HEALTH MALAYSIA

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Preface

This Guidance Document was prepared by the Medical Device Authority (MDA) to help the industry and healthcare professionals in their quest to comply with the Medical Device Act (Act 737) and the regulations under it.

This Guidance Document shall be read in conjunction with the current laws and regulations used in Malaysia, which include but not limited to the following-

a) Medical Device Act 2012 (Act 737); and

b) Medical Device Regulations 2012;

In this Guidance Document, the following verbal forms are used:

— “shall” indicates a requirement;

— “should” indicates a recommendation;

— “may” indicates a permission; and

— “can” indicates a possibility or a capability.

When a requirement is required to be “documented”, it is also required to be established, implemented and maintained.

Irrespective of the requirements of this Guidance Document, MDA has the right to request for information or material, or define conditions not specifically described in this document that is deemed necessary for the purpose of regulatory control.

MDA has put much effort to ensure the accuracy and completeness of this guidance document. In the event of any contradiction between the contents of this document and any written law, the latter should take precedence.

MDA reserves the right to amend any part of the guidance document from time to time.

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MEDICAL FACE MASK AND RESPIRATORS

0 Introduction

It is necessary to protect public health and patient safety by ensuring that all medical devices in the Malaysian market meet appropriate standards of safety, quality, performance and effectiveness, and that they are used safely.

They are many types of masks that are available in the Malaysian market that offer a range of protection against potential health hazards. Face masks and respirators are regulated as medical devices if there are claims or descriptions by the manufacturer that makes the mask or respirator a medical device as defined in Section 2 of Act 737.

Generally, face masks fall within this definition are intended for prevention of the transmission of disease (including uses related to COVID-19) and for medical purpose such as for surgical, clinical or use in other health services. Medical masks are regulated as Class A medical devices.

If the manufacturer's labelling, advertising, or documentation contain the claims above, the face mask is considered to be a medical device and is required to be registered with the Authority. This publication is intended to provide clarification on medical face masks and respirators that are regulated under the Medical Device Act (Act 737).

According to World Health Organisation (WHO), medical face mask is divided into two categories, which is procedure mask and surgical mask. Both, are used in clinical/health care setting. This guidance document will specify the requirements for both face mask/respirators.

Also available in the Malaysia market are non-medical face mask. Basically, non-medical face masks marketed to the general public for general use, non-medical purposes, such as use in construction and other industrial applications, are not medical devices. These types of face masks such as reusable cloth masks, fabric face mask or single-use face masks are not intended for use in a clinical setting or explicitly to prevent the transmission of disease between persons.

A non-medical respirator is a respiratory protective device designed to achieve a very close facial fit and very efficient filtration of airborne particles. These respirators intended for use in industrial settings such as construction sites or factories to protect workers from dust and debris.

Both non-medical face mask and respirator is classified as personal protective equipment (PPE) and are not regulated by MDA.

1 Scope and application

This guidance document specifies the requirements for medical face masks and respirators that are regulated under the Medical Device Act (Act 737). This document is applicable to establishments, healthcare facilities, and public dealing with medical face mask and respirators.

2 Normative references

MS EN 14683, *Medical Face Masks- Requirements and test methods*

ASTM F2100-19, *Standard Specification for Performance of Materials Used in Medical Face Masks*

YY/T 0969*, Single-use Medical Face Mask*

YY/T 0469, *Surgical Masks*

3 Terms and definitions

For the purposes of this document, the terms and definitions in Act 737, the regulations under it and the following apply.

3.1 face mask

a flexible, loose-fitting mask designed to be placed over the mouth and/or nose and chin fitted with the head harness which can be head or ears attachment of a wearer to permit normal breathing while protecting the wearer from the transfer of particles from the environment.

3.2 respirator

respiratory protective device designed to achieve a very close facial fit and very efficient filtration of airborne particles.

4 Requirements

An application for the registration of a medical device shall be made according to the requirements in Act 737 and in the manner determined by the Authority in Medical Device Regulations 2012. The person responsible for registering a medical device under Act 737 is the manufacturer or the authorized representative. Table 1 shows the minimum requirements for medical face masks and respirators.

Table 1. Requirements for medical face masks and respirators

Type of medical face mask/ respirator	Description	Minimum performance and labelling requirements
Procedure mask/ respirator	A procedure mask is used for performing patient procedures, or when patients are in isolation (Clean environments, sterile cores, processing departments, ER and ICU for bedside procedures, etc.) to reduce the risk of spread of infections.	• Shall comply with all the requirements in **EN 14683:2019***:* At least comply with requirements and Test Methods **'Type I' or Type II** or **ASTM F2100-19 'Level 1'** or **YY/T 0969 with ≥95% BFE** or any equivalent standard giving comparable performance. • Shall comply with Requirements for Labelling of Medical Devices and

Type of medical face mask/ respirator	Description	Minimum performance and labelling requirements
		should have description of mask and BFE (%).
Surgical mask/ respirator – Fluid resistant	A surgical mask is used inside the operating room or within other sterile procedure areas to protect the patient environment from contamination. It is also intended to **protect the wearer against splashes** of potentially contaminated liquids	• Shall comply with all the requirements in **EN 14683 'Type IIR'** or **ASTM F2100-19 'Level 2 or 3'** or **YY/T 0469 with ≥98% BFE** or any equivalent standard giving comparable performance • Shall comply with Requirements for Labelling of Medical Devices and should be labelled 'Type IIR' or 'Level 2 or 3' or have description of mask (such as 'splash' or 'fluid resistant') and BFE (%).

5 Performance Characteristics

Table 2. Comparison on test requirements based on EN 14683:2019, ASTM F2100-19, YY 0469 and YY 0969

		EN 14683:2019 MEDICAL FACE MASKS – REQUIREMENTS AND TEST METHODS			ASTM F2100-19 STANDARD SPECIFICATION FOR PERFORMANCE OF MATERIALS USED IN MEDICAL FACE MASKS			YY 0469 China Standard Surgical Mask	YY 0969 China Standard Single-use medical face mask
		Type I	Type II	Type IIR	**Level 1**	**Level 2**	**Level 3**		
Barrier Testing	BFE %	≥95	≥98		≥95	≥98		≥95	≥95
	PFE %	Not required			≥95	≥98		N/A	N/A
	Synthetic Blood	Not required	Pass at ≥ 16.0 kPa(>120mmHg)		Pass 80 mmHg	Pass at 120 mmHg	Pass at 160 mmHg	Pass at 120 mmHg	N/A
Physical Testing	Differential Pressure	<40 Pa/cm^2	<60 Pa/cm^2		<5.0 mmH_2O/cm^2	<6.0 mmH_2O/cm^2		<49 Pa/cm^2	<49 Pa/cm^2
Safety Testing	Flammability	See European Medical Directive (2007/47/EC, MDD 93/42/EEC)			Class 1 (≥ 3.5 seconds)			N/A	N/A
	Microbial Cleanliness	≤30 cfu/g			Not required			≤100 cfu/g	≤100 cfu/g
	Biocompatibility	Complete an evaluation according to ISO 10993			510 K Guidance recommends testing to ISO 10993				
Sampling ANSI/ASQC Z1.4 ISO 2859-1		• Minimum of 5 masks up to an AQL of 4% for BFE, Delta P and Microbial Cleanliness • 32 masks for Synthetic Blood (Pass = ≥29 passing, Fail = ≤28 passing)			• AQL 4% for BFE, PFE, Delta P • 32 masks for Synthetic Blood (Pass = ≥29 passing, Fail = ≤28 passing) • 14 masks for Flammability				

6 Registration Requirements

For the purpose of registration, the establishment shall submit the complete test report to the Authority during registration process.

Annex A
(Informative)

Pictures of a face mask and respirator

The pictures below demonstrate the difference in physical characteristics between a face mask and a respirator.

Face mask

Respirator

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