MDA/GD/0033

October 2021

Second Edition

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.

Contents **Page**

Preface iii

0 Introduction 1

1 Scope and application 1

2 Term and definition 2

3 Requirements 2

4 Performance Characteristics 3

5 Registration requirement 3

Annex A WHO Recommendation 4

Annex B Face mask and Respirators 6

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.

CONTACT INFORMATION

For further information, please contact:

MEDICAL DEVICE AUTHORITY
Ministry of Health Malaysia
Level 6, Prima 9, Prima Avenue II

Block 3547, Persiaran APEC
63000 Cyberjaya, Selangor
MALAYSIA
T: (03) 8230 0300
F: (03) 8230 0200
Website:mda.gov.my

DISTRIBUTION RECORDS

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 was 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, nonmedical 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. A face mask that is not intended to be used in a clinical setting or explicitly to prevent the spread of diseases between people and does not meet a medical device standard is not a medical device.

A non-medical respirator is a respiratory protective device designed to achieve a very close facial fit and very efficient filtration of airborne particles. Respirators intended for

use in industrial settings such as construction sites or factories to protect workers from dust and debris. Therefore, respirator also not a medical device and are not regulated by MDA.

Both non-medical face mask and respirator is classified as personal protective equipment (PPE) and can be manufactured and supplied without needing to be registered with the Authority.

1 Scope and application

This guideline intended to provide clarification on 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 Term and definition

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

2.1 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.

2.2 Respirator

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

3 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 Requirements for medical face mask and respirator

Type of Medical Face Masks/Respirators	Description	Minimum Performance and Labelling Requirements
Procedure mask/Respirators	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 Medical Face Masks: At least comply with requirements and Test Methods **'Type I' or Type II** or ASTM F2100-19 Standard Specification for Performance of Materials Used in Medical Face Masks **'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 should have description of mask and BFE (%).

Surgical mask/Respirators – Fluid resistant - surgical masks	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 14683:2019 Medical Face Masks: Requirements and Test Methods **'Type IIR'** or ASTM F2100-19 Standard Specification for Performance of Materials Used in Medical Face Masks **'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 (%).

4 Performance Characteristics

		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 Singleuse 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		

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

5 Registration Requirements

Although class A registration does not require an assessment from the CAB. However, for the purpose of registration, the establishment shall submit the complete test report to the Authority during registration process.

Annex A

(Informative)

WHO RECOMMENDATIONS

WHO has made recommendation type of mask or respirator to be used for use by healthcare personnel depending on transmission scenario, setting and activity as shown **Table 3 below:**

COVID-19 Transmission scenario	Who	Setting	Activity	What type of mask
Known or suspected community transmission	Health worker** or caregiver	Health facility (including primary, secondary, tertiary care levels, outpatient care, and LTCF)	In patient care area – irrespective if patients are COVID-19 suspect/confirmed	Medical mask (targeted continuous medical masking)
	Personnel (working in health care facilities but not providing care for patients, e.g. administrative staff)	Health care facility (including primary, secondary, tertiary care levels, outpatient care, and LTCF)	No routine activities in patient areas	Medical mask not needed. Medical mask should be considered only if in contact or within 1m of patients, or according to local risk assessment.

	Health worker	Home visit (for example, for antenatal or postnatal care, or for a chronic condition)	When in direct contact or when a distance of at least 1m cannot be maintained.	Consider using a medical mask
	Health worker	Community	Community outreach programs	Consider using a medical mask
Sporadic transmission or clusters of COVID-19 cases	Health worker or caregiver	Health care facility (including primary, secondary, tertiary care levels, outpatient care, and LTCF)	Providing any patient care	Medical mask use according to standard and transmissionbased precautions (risk assessment)
	Health worker	Community	Community outreach programs	No mask needed
Any transmission scenario	Health worker or caregiver	Health care facility (including primary, secondary, tertiary care levels,	When in contact with suspect or confirmed COVID-19 patient	Medical mask
COVID-19 Transmission scenario	**Who**	**Setting**	**Activity**	**What type of mask**
		outpatient care, and LTCF)		
	Health worker	Health care facility (including LTCF), in settings where aerosol generating procedures (AGP) are performed	Performing an AGP on a suspected or confirmed COVID-19 patient or providing care in a setting where AGPs are in place for COVID19 patients.	Respirator (N95 or N99 or FFP2 or FFP3)
	Health worker or caregiver	Home care	When in close contact or when a distance of at least 1 m cannot be maintained from a suspect or confirmed COVID-19 patient	Medical mask

*This table refers only to the use of medical masks and respirators. The use of medical masks and respirators may need to be combined with other personal protective equipment and other measures as appropriate, and always with hand hygiene.

**Health workers are all people primarily engaged in actions with the primary intent of enhancing health. Examples are: Nursing and midwifery professionals, doctors, cleaners, other staff who work in health facilities, social workers, and community health workers, etc.

Annex B

(Informative)

Medical face mask and Respirators

Face mask

Respirators

MEDICAL DEVICE AUTHORITY

MINISTRY OF HEALTH, MALAYSIA

Contact Information:

MEDICAL DEVICE AUTHORITY
Ministry of Health Malaysia
Level 6, Prima 9, Prima Avenue II
Block 3547, Persiaran APEC
63000 Cyberjaya, Selangor
MALAYSIA
T: (03) 8230 0300
F: (03) 8230 0200
Website:mda.gov.my

Medical Device
AUTHORITY
MALAYSIA