MDA/GD/0033
May 2023
Third Edition

MEDICAL DEVICE GUIDANCE DOCUMENT

MEDICAL FACE MASK AND RESPIRATOR

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);

b) Medical Device Regulations 2012;

c) Medical Device (Duties and Obligations of Establishments) Regulations 2019; and

d) Medical Device (Advertising) Regulations 2019.

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

1 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, 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. 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.

2 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.

3 Term and definition

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

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 (>120 mmHg)	Pass at 80 mmHg	Pass at 120 mmHg	Pass at 160 mmHg	Pass at 120 mmHg	N/A
Physical Testing	Differential Pressure	<40 Pa/cm2		<60 Pa/cm2	<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 MedicalDirective (2007/47/EC, MDD93/42/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 Z1.4ISO 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

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:

Table 3 Mask use in health care settings depending on transmission scenario, target population, setting, activity and type

COVID-19 Transmission scenario	Who	Setting	Activity	What type of mask
Known or suspected community or cluster transmission of SARS-CoV-2	Health worker and caregiver	Health facility (including primary, secondary, tertiary care levels, outpatient care, and long-term care facilities)	For any activity in patient-care areas (COVID-19 or non-COVID-19 patients (e.g., cafeteria, staff rooms)	Medical mask (or respirator if aerosol generating procedures performed)
	Other staff, patients, visitors, service suppliers		For any activity or in any common area	Medical or fabric mask Consider using amedical mask
	Inpatients	In single or multiple-bed rooms	Where physical distance of at least 1 metre cannot be maintained	
	Health workers and caregivers	Home visit (for example, for antenatal or postnatal care, or for a chronic condition)	When in direct contact with a patient or when a distance of at least 1 metre cannot be maintained	Medical mask
		Community	Community outreach programs/essential routine services	
Known or suspected sporadic transmission of SARS-CoV-2 cases	Health workers and caregivers	Health facility (including primary, secondary, tertiary care levels, outpatient care, and long-term care facilities)	In patient care-area irrespective of whether patients have suspected/confirmed COVID-19	Medical mask
	Other staff, patients, visitors, service suppliers and all others		No routine activities in patient areas	Medical mask not required. Medical mask should be worn in contact or within 1 meter of patients, or according to local risk assessment
	Health workers and caregivers	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 1 metre cannot be maintained	Medical mask
		Community	Community outreach programs (e.g., bed net distribution)	

No documented SARS-CoV-2 transmission	Health workers and caregivers	Health carefacility (including primary, secondary, tertiary care levels, outpatientcare, and long-term care facilities)	Providing any patient care	Medical mask uses according to standard and transmission-based precautions
		Community	Community outreach programs	
Any transmission scenario	Health workers	Health care facility (including primary, secondary, tertiary care levels, outpatient care, and long-term care facilities), 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 COVID- 19 patients.	Respirator (N95 or N99 or FFP2 orFFP3)

NOTE: *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.

[SOURCE: World Health Regulations (WHO). (I December 2020) *Mask use in the context of Covid-19.* Retrieved from https://apps.who.int/iris/bitstream/handle/10665/337199/WHO-2019-nCov-IPC_Masks-2020.5-eng.pdf?sequence=1&isAllowed=y

Annex B
(Informative)

Medical face mask and Respirators

Face mask

Respirators

MEDICAL DEVICE AUTHORITY

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