MDA/GD/0058
10 May 2022
Second Edition

MEDICAL DEVICE GUIDANCE DOCUMENT

PERSONAL PROTECTIVE EQUIPMENT (PPE) - REQUIREMENTS

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 2012 (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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PERSONAL PROTECTIVE EQUIPMENT (PPE) – REQUIREMENTS

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.

There are many types of Personal Protective Equipment (PPE) that are available in the Malaysian market that offer a range of protection against potential health hazards. A PPE are regulated as medical devices if there are claims or descriptions by the manufacturer that makes the PPE a medical device as defined in Section 2 of Act 737.

Generally, PPE 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.

If the manufacturer's labelling, advertising, or documentation contain the claims above, the PPE is considered to be a medical device and is required to be registered with the Authority. This publication is intended to provide clarification on PPE that are regulated under the Medical Device Act 2012 (Act 737).

PPE used in healthcare institution includes, medical facemask/respirator, surgical facemask/respirator, non-surgical gowns, surgical gowns, coverall, medical glove, head shoe cover, face shield and goggle.

Also available in the Malaysia market are non-medical PPE. Basically, non-medical PPE marketed to the high-risk industry/worker to protect them from industrial hazard, and for non-medical purposes, such as use in construction, chemical handling in industry, and other industrial applications, are not medical devices. These types of PPE are not intended for use in a clinical setting or explicitly to prevent the transmission of disease between persons.

Non-medical PPE such as those used in construction and other industrial applications are not regulated by MDA.

This guidance document is will provide useful information on medical PPE to establishments, healthcare facilities, and public dealing with PPE.

2 Scope and application

This guidance document specifies requirements for Personal Protective Equipment (PPE) that fit the definition of medical device in accordance with Section 2 of the Medical Device Act 2012 (Act 737).

This guidance document is applicable to establishments, and healthcare facilities, dealing with PPE.

3 Normative references

The following normative references are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the normative reference (including any amendments) applies.

ANSI/AAMI PB70 Liquid barrier performance and classification of protective apparel and drapes intended for use in health care facilities;

ASTM D6319 - Specification for Nitrile Examination Gloves for Medical Application;

ASTM D3578 - Standard Specification for Rubber Examination Gloves;

ASTM D5250 - Standard Specification for Poly (vinyl chloride) Gloves for Medical Application;

ASTM D6977 - Standard Specification for Polychloroprene Examination Gloves for Medical Application;

ASTM D6400 - Standard Specification for Labelling of Plastics Designed to be Aerobically Composted in Municipal or Industrial Facilities;

ASTM D3577 - Standard Specification for Rubber Surgical Gloves;

ASTM F2407 – Standard Specification for Surgical Gowns Intended for Use in Healthcare Facilities

EN 13688 – Protective clothing - General Requirements

EN 13795 Surgical clothing and drapes - Requirements and test methods - Part 1:Surgical drapes and gowns;

EN 14126 Protective clothing - Performance requirements and tests methods for protective clothing against infective agents;

EN 455- Medical gloves for single use;

EN 556 Sterilization of medical devices. Requirements for medical devices to be designated "STERILE";

EN 13432 Packaging. Requirements for packaging recoverable through composting and biodegradation. Test scheme and evaluation criteria for the final acceptance of packaging;

EN166 - Personal Eye Protection Standard

ISO 16603 Clothing for protection against contact with blood and body fluids - Determination of the resistance of protective clothing materials to penetration by blood and body fluids - Test method using synthetic blood;

ISO 16604:2004 Clothing for protection against contact with blood and body fluids - Determination of resistance of protective clothing materials to penetration by blood-borne pathogens - Test method using Phi-X 174 bacteriophage;

ISO 22610 Surgical drapes, gowns and clean air suits, used as medical devices, for patients, clinical staff and equipment - Test method to determine the resistanceto wet bacterial penetration;

ISO 22612 Clothing for protection against infectious agents - Test method for resistance to dry microbial penetration;

ISO 11607-1:2019 - Packaging for terminally sterilized medical devices.

ISO 811:2018 Textiles - Determination of resistance to water penetration - Hydrostatic pressure test;

ISO 11193-1:2020 Single-use medical examination gloves - Part 1: Specification for gloves made from rubber latex or rubber solution;

ISO 10282 Single-use sterile rubber surgical gloves - Specification

ISO 10993-10:2010 Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization;

ISO 10993-23:2021 Biological evaluation of medical devices - Part 23: Tests for irritation;

ISO 7765-1 Plastics film and sheeting - Determination of impact resistance by the free-falling dart method - Part 1: Staircase methods

ISO 6383-2 Plastics - Film and sheeting - Determination of tear resistance - Part 2: Elmendorf method

ISO 13688 Protective clothing - General requirements

ISO 11193-1:2020 Single-Use Medical Examination Gloves - Part 1: Specification for gloves made from rubber latex or rubber solution

ISO 11193-2:2006 Single-Use Medical Examination Gloves - Part 2: Specification for gloves made from poly (vinyl chloride)

4 Terms and definitions

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

4.1 level of risk

Level 1 is minimal risk, to be used, for example, during basic care, standard isolation, cover gown for visitors, or in a standard medical unit.

Level 2 is low risk, to be used, for example, during blood draw, suturing, in the Intensive Care Unit (ICU), or a pathology lab.

Level 3 is moderate risk, to be used, for example, during arterial blood draw, inserting an Intravenous (IV) line, in the Emergency Room, or for trauma cases.

Level 4 is high risk, to be used, for example, during long, fluid intense procedures, surgery, when pathogen resistance is needed or infectious diseases are suspected (non-airborne).

4.2 non-surgical

A medical treatment that does not involve cutting open the body

4.3 Personal Protective Equipment (PPE)

An equipment designed to protect the wearer from injury or the spread of infection or illness.

4.4 non-surgical

A medical procedure involving an incision with instruments; performed to repair damage or arrest disease in a living body.

5 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 an authorized representative.

All PPE listed in table 1, is classified as a medical device if the intended use can fit the definition in Section 2 of Act 737.

Table 1. Minimum requirements for PPE (Non-Surgical Gown, Surgical Gown, Others Apparels & Coverall)

Type of Medical Personal Protective Equipment	Description	Minimum Performance and Labelling Requirements
Non-surgical Gowns 	A non-surgical gown 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 Non-surgical gowns are not worn during surgical procedures, invasive procedures, or when there is a medium to high risk of contamination.	• ANSI/AAMI PB70: At least comply with requirements and test method for **'Level 1'** or **'Level 2'**; or • EN 13795; and • Shall comply with Requirements for Labelling of Medical Devices and should have description of non-surgical Gowns and level applied.
Surgical Gowns/Isolation Gowns 	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 penetration by blood-borne pathogens** Surgical gowns are used when there is a medium to high risk of contamination and a need for larger critical zones	• ANSI/AAMI PB70: At least comply with requirements and test method for **'Level 3'** or recommended **'Level4**'; or • EN 13795; and • EN 556, if sterile, or alternative equivalent set of standards; and • Shall comply with Requirements for Labelling of Medical Devices and should have description of Surgical Gowns/Isolation gown andlevel applied.

Type of Medical Personal Protective Equipment	Description	Minimum Performance and Labelling Requirements
Coveralls 	Protective clothing against infective agents measures the ability of a suit or gown to protect users against bacteria,fungi and viruses; Used in high-risk situation and/or in high- risk environment (pandemic situation) to protect the wearer from the transfer of microorganisms by blood and body fluids.	• EN 14126; and • ISO 16603 (Class 5 or 6); and • ISO 16604 (Class 5 or 6); or • EN 13795; and • ISO 22610 (high performance); and • ISO 22612 (high performance); or • At least ANSI/AAMI PB70 Level 4; and • Shall comply with Requirements for Labelling of Medical Devices and should have description of Coverall and Class.
Apron 	Used for performing patient procedures, orwhen 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 Apron are not worn during surgical procedures, invasive procedures, or whenthere is a medium to high risk of contamination.	• EN 14126; or • At least ANSI/AAMI PB70 level 1 or 2; or • ASTM F2407 level 1 or 2; or • EN 13688; and For impact strength and tear resistance: • ISO 7765-1; and • ISO 6383-2. If biodegradable: • EN 13432; or • ASTM D6400; and • Shall comply with Requirements for Labelling of Medical Devices and should have description for medical use.

Type of Medical Personal Protective Equipment	Description	Minimum Performance and Labelling Requirements
Head Cover 	As a two-way protective barrier of patient/healthcare providers during patient examination/treatment against contaminants.	• ISO 13688; and • EN 14126; and If biodegradable: • EN 13432; or • ASTM D6400; and • Shall comply with Requirements for Labelling of Medical Devices and should have description for medical use.
Shoe Cover 	Shoe covers are important as they help maintain a sanitary environment by eliminating tracked-in dirt and microbesand they protect the wearer fromaccidental spills and bodily fluids. Generally used in hospital to prevent the wearer's skin and mucous membranes from becoming contaminated or to reduce environmental exposure and as a protective barrier to prevent foreign particles from entering into operation theatre or clean room and hygienic area.	• EN 14126; and • ISO 13688 If biodegradable: • EN 13432; or • ASTM D6400; and • Shall comply with Requirements for Labelling of Medical Devices and should have description for medical use.
Gloves, medical examination (nonsterile) 	Medical examination gloves are used for preventing contamination between caregivers and patients. These gloves are used during procedures that do not requiresterile conditions, for example drawing blood for a blood test. Some of these gloves can also protect the wearer from harm caused by dangerous chemicals or pharmaceuticals.	• ISO 11193 all parts, as appropriate; or • EN 455 all parts, or • ASTM D6319, D3578, D5250, or • D6977 (as appropriate); and • Shall comply with Requirements for Labelling of Medical Devices and should have description of medical examination gloves and nonsterile.

Type of Medical Personal Protective Equipment	Description	Minimum Performance and Labelling Requirements
Gloves, surgical (sterile) 	Surgical gloves are to act as a protective barrier to prevent the possible transmission of diseases between healthcare professionals and patients during surgical procedures.	• ISO 10282; or • EN 455 all parts; or • ASTM D3577 • For Sterility: ISO 11607; and • Shall comply with Requirements for Labelling of Medical Devices and should have description of surgical gloves and sterile.
Face Shield 	The face shields are intended by the manufacturer to be used alone for a human being for prevention of disease by **protecting an eye** from splash, dropletfrom the human body Face shield is used by the healthcare professional during surgical procedures, invasive procedures, or when there is a medium to high risk of contamination suchas handling covid-19 cases.	• EN166 or alternative equivalent standard; and • ISO 10993-10; and • ISO 10993-23; and • Shall comply with Requirements for Labelling of Medical Devices and should have description of is used by healthcare professional to protect an eye during medical procedure.
Goggle 	The goggle is intended by the manufacturer to be used alone for a human being for prevention of disease by **protecting an eye** from splash, dropletfrom the human body Goggle is used by the healthcare professional during surgical procedures,invasive procedures, or when there is a medium to high risk of contamination such as handling covid-19 cases.	• EN166 or alternative equivalent standard; and • ISO 10993-10; and • ISO 10993-23; and • Shall comply with Requirements for Labelling of Medical Devices and should have description of is used by healthcare professional to protect an eye during medical procedure.

* Photos for illustration purpose only

6 Registration Requirements

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

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