

Public Health (Standards for Personal Protective Apparel,
Materials and Equipment) Regulations, 2020

IT is hereby notified that the Minister of Health and Child Welfare has, in terms of section 137 of the Public Health Act [*Chapter 15:17*], made the following regulations:—

Title

1. These regulations may be cited as the Public Health (Standards for Personal Protective Apparel, Materials and Equipment) Regulations, 2020.

Application

2. (1) These regulations apply to the standards required for the manufacture, sale and other disposal of apparel, materials and equipment intended to be worn or used as protection against any formidable infectious disease by different categories of persons in their interaction with members of the public.

(2) The aforementioned standards are specified in the Schedule.

Interpretation

3. (1) In these regulations—

“personal protective apparel, materials and equipment” means apparel, materials and equipment useful in preventing the transmission of COVID-19 or any other formidable infectious disease, such as face masks, gowns, disinfectants, detergents, hand sanitizers, overshoes, aprons, goggles, ventilators, thermometers receptacles for dispensing sanitizers or disinfectants, and surgical or other gloves;

“non-standard personal protective apparel, materials and equipment” means anti-infectious apparel, materials and equipment, that are not manufactured to the appropriate standard specified in the Schedule.

Prohibition against sale, etc., of non-standard personal protective apparel, materials and equipment

4. (1) No person shall—

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- (a) offer for sale or attempt to offer for sale; or
- (b) sell by auction; or
- (c) expose, display or advertise for sale; or
- (d) sell under an agreement in terms of the Hire-Purchase Act [*Chapter 14:11*] or by means of staggered payments or instalments; or
- (e) transmit, convey, deliver, distribute, possess or prepare for sale; or
- (f) barter or otherwise exchange or dispose of for valuable consideration; or
- (g) import or export; or
- (h) donate or otherwise dispose of for use by others; or
- (i) manufacture, assemble or fabricate;
non-standard personal protective apparel, materials or equipment.

(2) Any person who contravenes subsection (1) shall be guilty of an offence and liable to fine not exceeding level twelve or to imprisonment for a period not exceeding one year to both such fine and such imprisonment.

(3) In the case of a company or other corporate body, the directors or members of the governing body shall each be liable together with the such company or body to the penalties specified in subsection (2).

SCHEDULE (*Section 2(2)*)

STANDARD PERSONAL PROTECTIVE APPAREL, AGENTS AND EQUIPMENT

(Key: AS = Australian Standards'; AFNOR = French Association for Standardisation; EN = European Union Standards, ISO = International Organisation for Standardisation; NZA = New Zealand Standards; ZW = Zimbabwe Standards; US Standards = United States Standards; PPE = Personal Protective Equipment).

Face masks	Comment
1. AFNOR Spec S76-001 2020+ Annex C (Patterns)	For general public and workers not directly dealing with Covid-19 or other patients suffering from a formidable infectious diseases (unless filtering masks are available

2. General Masks, EN 149	AFNOR- SPEC- S76-001 Barriers Masks- Guide to minimum requirements, methods of testing of testing, making and use- general use This standard is for use by manufacturers to ensure best practice in production and quality control but not for certification and quality control but not for certification purpose Certification of products shall be against EN 149
3. EN 149 2009 Respiratory protective devices- Filtering half masks to protect against	For people in contract with contaminated people (priority given to healthcare people). Masks protecting the user by filtering the air, not allowing COVID-19 or other formidable infectious agent (From level FFP2)
4. Medical Respiratory Products (Surgical Face Masks and Respirators)	BS EN 14683 ASTM 2100 (Materials for use in medical face masks)
5. EN 14683: 2019 EN Medical face masks- Requirements and best method	Known as “Surgical Masks”
<i>Below are other standards for masks for people in contact with contaminated people (priority given to healthcare people)</i>	
6. NIOSH-42 CFR Part 84 Respiratory Protective Devices	US Standard (from N95 level)
7. GB 2626- 2029 Respiratory protection- Non- powered air-purifying particle respirator	Chinese Standard (from KN95 level)
8. AS/NZA 1716: 2012	AS/NZA (from P2 level)
9. KMOEL – 2027- 64	South Korea (for 1st class)
10. JMHL W- Notification 214, 2018	Japan (from DS)
Gloves	
1. ISO 374- 5: 2016. Protective gloves against dangerous chemicals and micro-organisms- Part 5: Terminology and performance requirements for micro-organisms risk	

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2. EN 455-1: 2000 Medical gloves for single use- Part 1: Requirements and testing for freedom from holes (MDD)	
3. EN 455- 2: 2015 Medical gloves for single use- Part 2: Requirements and testing for physical properties (MMD)	
4. EN 455- 2: 2015 Medical gloves for single use- Part 3: Requirements and testing for biological evaluation	
5. Protective clothing- Gloves	ISO 11193-1 ISO 10282
6. EN-455-4: 2009 EN Medical gloves for single use- Part 4: Requirements and testing for shelf life determination (MDD)	
Clothing	
1. ISO 13688: 2013, Protective Clothing – General requirements	
2. EN 14126: 2003 Protective clothing- Performance requirements and test methods for protective clothing against infective agents	
3. EN 14605: 2009 Protective clothing against liquid chemicals- performance requirements for clothing with liquid-tight (Type 3) or spray-tight (Type 4) connections, including items providing protection to parts of the body only	

4. EN 13795- 1: 2019 Surgical clothing and drapes- Requirements and test methods- Part 1: Surgical drapes and gowns	
5. EN 13795- 2: 2019 Surgical drapes, gowns and clean air suits, used as medical devices for patients, clinical staff and equipment- Part 2: Test methods	
Hand Biocid (against formidable infectious agents)	
1. Guide to Local Production: WHO-recommended Handrub Formulations	For urgency domestic production
2. EN 14476: 2013 + A2: 2019 Chemical disinfectants and antiseptics	Quantitative suspension test for the evaluation of virocidal activity in the medical area. Test method and requirements
SANITIZER	
1. Hand Sanitizers (Alcohol Based)	ARS ZW HS 1470
Other	
1. Respiratory Products (Surgical Face Masks and Respirators)	ZWS 657
2. Protective Clothing- Gowns- Overshoes- Plastic Aprons- Goggles- Scrubs	ISO 13688 (General requirements for PPEs)
3. Protective Clothing- Gloves	ISO 11193-1 ISO 19282
4. Emergency Ventilators (installed in rescue vehicles)	ISO 10651-3
5. Portable Ventilators (for use in emergency and transport)	ISO 10651-3
6. Temperature Measuring Devices	1. Fluke Temperature Generator (Metrological Well) 2. Fluke Water Bath 3. Infra-Red (IR) Temperature Gun
7. Chemicals for Use in the Food Industry (Detergents and Disinfectants)	1. EN 166:2001 Personal eye-protection- Specifications

