PROTECTIVE EQUIPMENT AND MATERIAL STANDARDS

1. INTRODUCTION

Personal protective material whose role is the protection of the user from exposure to exudate from other people and the environment in general play an important role for health care workers.

Personal Protective materials including Medical Use face masks N95, Surgical use face masks and protective overalls are Medical Devices classified as Class A- In accordance to the rule-based classification by International Medical Devices Forum. In this regard, the International standards Organization standards used internationally are also considered in Kenya in the regulatory framework for Medical Devices.
The N95 Respirator masks are designed to achieve close facial fit for efficient filtration of air-borne particles; and if used properly the masks have capacity to eliminate 95% of very small test particles (0.3% micron). These respirators are not recommended for use by the public as they require close fitting on the device to the mouth and nose of the user. This can also cause difficulty breathing for persons with medical conditions and respiratory diseases.
The main manufacturers of the N95 respirators are in china, with others spread in the Americas.

Googles and protective coats also used as protective wears use the same international standard organization ISO 22609 to test against resistance from splatter or splashing or blood, body fluids and other potentially infectious materials.
Both the N95 Masks, googles, and protective wear are subjected to rigorous regulatory process before market entry is granted for the market authorization holder. Below are the requirements for considerations of market entry by applicants for class A Medical Devices;

- Certificate of registration from the country of Origin National Regulatory Authority (China FDA in this case)
- Certificate of analysis from the manufacturing site for the item manufactured in accordance to the ISO standard requirement
- ISO 13485 (ISO Standard for Quality management of Medical Devices) Manufacturing site audit assessment
- Import permit clearance
- Conformity assessment by the Kenya Bureau of Standards (KEBs) before release of goods from the Country of Origin.

Kenya relies on importation of goods from countries including China for personal protective materials with the above requirements mandatory for market authorization to be granted.

2. TECHNICAL SPECIFICATION FOR SURGICAL MASKS

2.1 General Description

Surgical masks latex free, fiber glass free, hypo-allergic, with ear loops and nose piece, Box of 100

Synonym: Procedure /face masks

2.2 Intended Use:

Surgical mask is intended to be worn by medical personnel during surgical or other medical procedures to protect both the patient and the operating personnel from transfer of microorganisms, body fluid and particulate material transfer

2.3 Technical Specifications

Latex Free, Hypoallergenic, Fiberglass fee, Fluid Resistant, Three Ply construction. 3 pleats of folds to allow the user to expand the mask so it covers the area from the nose to the chin. Mask should be secured with an ear loop to be placed behind the ears. >99% Bacterial Filtration Efficiency (BFE) at 5-micron capacity; >95% Bacteria Filtration Efficiency (BFE) at 3-micron capacity. Reduces exposure to blood and body fluids. Minimizes patient contamination to exhaled microorganisms. This product is intended for use in infection control practices.

a) Material; Spunbound polypropylene for inner and outer facings of mask. Three (3) ply, fluid resistant, Fiberglass free, latex free mask **Colour;** Blue

b) Usage; For Single use only

c) Size selected: Total length: approximately 175mm. Width: approximately 90mm.

c) Primary packaging: Unit of use (1) box of 100 masks

d) **Secondary packaging:** 6 cases of 100 masks /box (600 pieces/case 1

e) Labelling on the primary packaging:

Name and/or trademark of the manufacturer. Manufacturer's product reference. Type of product and main characteristics. If the packaging is not transparent, it must bear a diagram (preferably actual size) showing the essential parts of the product and indicating the position of the product in the packaging. Lot number prefixed by the word "LOT" (or equivalent harmonized symbol) (if applicable). Expiry date by year and month, prefixed by the word "EXP" (or equivalent harmonized symbol) (if applicable). The words "for single use" (or equivalent harmonized symbol). The words "destroy after use" (if space allows). Number of units per primary packaging (if applicable). Information for particular storage conditions (temperature, pressure, light, humidity, etc.), as appropriate (or equivalent harmonized symbol). The word single use with equivalent harmonized symbol should be stated and the Manufacturer's instruction for use.

Personal Protective Equipment standard, specification and Norms

Target protection Area	**PPE Component**	**PPE Component for Community care Center**
Body Full body	Coverall, hood, apron	
Partial body		Gown, hood, Apron
Mucosae		
Eyes	Googles, face shield	Googles, face shield
Nose	Respirator, face mask	Respirator, face mask
Mouth		
Proximities		
Hands	Gloves	Gloves
Feet	Boots	Boots

1. **Full Body Protection: Coveralls (1)**
   Context of use - Used for Isolation high risk areas within Corona Treatment Unit (CTU)/ Holding Center

   Short specifications
   - Disposable, single-use liquid-penetration resistant, biohazard-protective coverall with hood, for use in CVD(Corona Virus Disease) patient-isolation units suitable for stringent infection prevention and control practices and tested against viral penetration. Protective seams providing barrier equal to fabric.

Standards

- CE 89/686/EEC, Category III: Chemical protective coverall, Type 3B / Type 4B comply with EN14605:2005 +A1:2009 (or equivalent) marketing approval certificate - compliance with the EN 14126:2003 passing infectious agent test according to ISO 16604:2004 standard at minimum exposure pressure of 1.75kPa (class 2) (or equivalent international standard)

2. Full Body protection: Coveralls (2)

Context of use - Used for Isolation high risk areas within CTU/ Holding Center

Short specifications

- Coverall: Disposable, single-use, liquid-penetration resistant, biohazard protective coverall, co-packed with an apron/gown for use in CVD patient-isolation units suitable for infection prevention and control practices. - Apron: Gown designed with sleeves, for front protection with complete closure from the back and wrap around-waist ties. Elasticated cuffs. Shin length and below-Knee height.

Both Coverall and Apron are made of fabric that is infective agent tested against viral penetration at minimum 1.75kPa

Standards

- CE 89/686/EEC, Category III Type 6B comply EN 13034:2005 + A1:2009 (or equivalent)/ / 6PB comply with either EN 13034:2005 + A1:2009 or EN14605:2005 +A1:2009 (or equivalent) marketing approval certificate - Confirmation of compliance with the EN 14126:2003 passing infectious agent test according to ISO 16604:2004 standard at minimum exposure pressure of 1.75kPa (class 2) (or equivalent international standard)

3. **Partial body protections: Surgical gowns Standard/high performance EN 13795**

Context of use

- Lower risk areas such as Community Care Centers (CCCs), clinical care - dry area, other lower risk areas in HC facilities

Short specifications

- Surgical gown with long sleeves and a waist tie that binds at side or back
- Non-woven material (SMS*, SMMS*, etc.), reinforced in critical areas if HP gown
- size approx. 150 cm (W) x 130 cm (L)

- Single use, disposable

** Spunbond Meltblown Spunbond, commonly known as **SMS** is a tri laminate **non woven fabric**. It is made up of a top layer of spunbond polypropylene, a middle layer of meltblown polypropylene and a bottom layer of spunbond polypropylene*

Standards

CE 93/42: EN 13795 standard performance (SP) or high performance (HP)

Or equivalent

4. **Partial body protection: Aprons (disposable)**

Context

- Corona Treatment Units (CTUs) and CCCs over full or partial body protection

Short specifications

- Single use, sleeveless apron with adjustable back- and neck-band - Seamless, liquid proof and stain resistant - Material: durable environmentally friendly plastic, polyethylene (PE) - Size, approx.: 85 x 130 cm (w x l)
- Thickness: approx. 50 µ

Standards

- None yet identified

5.Partial body protection: Aprons (reusable)

Context

- Heavy duty (cleaning activities)

Short specifications

- Reusable sleeveless protective apron with adjustable back- and neck-band - Seamless liquid proof and stain resistant - Material: durable environmentally friendly plastic - Size, approx.: 120 x 145 cm (w x l)
- Thickness, approx.: 300 µ

Standards

- None yet identified

Refer to annex: PPE-Specification for Corona Virus presentation.