

## **ANNEX II – TECHNICAL SPECIFICATIONS**

### **1- Gown, surgical, nonsterile, nonwoven, disposable**

#### **Technical Specifications:**

- Surgical gown, with long sleeves, and a waist tie that binds at the side
- Fabric, non-woven material, f.e. SMS, SMMS, etc
- Outer layer liquid penetration resistant in critical areas (chest and sleeves)
- Length (measured at front from middle of neckline to bottom): 130 – 136 cm
- Circumference (measured at waist): 135–140 cm
- Sleeves finished with double layer cuff, cotton or synthetic, stretchy interlocked jersey, length: 4 - 8 cm
- Thumb/finger loops or elastic cuff to anchor sleeves in place
- Non-sterile or sterile
- Single use, disposable
- Size: M, L and XL

### **2- Coverall, protection, Category III, type 6b**

#### **Technical specifications**

- Elasticated hood around face
- Elasticated cuffs and ankles
- Sleeves with elasticated thumb loop
- Stitched or Bound seams
- Zipper with re-sealable flap protecting leakage through seams
- Stitched-in neck label indicating the type and performance of the suit against the below mentioned standards
- Color: White
- Material: Lightweight, do not contain rubber/ latex
- Antistatic treated on both sides
- Fabric is Infective agent tested against viral penetration at minimum 1.75kPa (class 2) (or equivalent international standard)
- Non-sterile
- Single Use, disposable
- Size: M, L and XL
- Primary packaging: Unit of use
- One coverall and one product information technical datasheet co-packed in a plastic bag

### **3- Mask, surgical, type IIR, tie strap, disposable**

#### **Technical specifications**

- Splash resistant, type IIR surgical mask
- Bacterial filtering efficiency: equal to or greater than 98%
- Breathing resistance: equal to or less than 49 Pa/cm<sup>2</sup>
- Splash resistance pressure: greater than 120 mmHg
- Fabric, non-woven with outer layer impervious liquid splash resistant material, f.e. polyethylene

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- Comprised of 3 or 4 non-woven layers, size adequately covering nose, mouth and chin
- Clearly identifiable inner and outer surfaces
- With attached 2 x 2 tie-straps, allowing correct fixation and securing at the back of the head
- Size: 15-19 cm x 9-11 cm (l x w)
- Non-sterile
- Single use, disposable
- Conform requirements of EU Medical Devices Directive 93/42, Class I (or equivalent internationally recognized marketing clearance)
- In specific, compliant with the EN 14683 standard for type IIR (or equivalent international standard)

### 4- Mask, high-filtration, FFP2/N95, nonsterile

#### Technical specifications

- Material: non-woven filter layer
- Filtration level: > 95 % for particles from 0.1 to 0.3 micron
- Air permeability: > 2 mm H<sub>2</sub>O
- Shape of the mask: duckbill, folded (horizontal) width-wise
- Respirator mask fits all face shapes, without inspiration/expiration air-leakage
- Upper edge has integrated easy malleable nose bridge strip reducing fogging of protective eye-wear
- Size nose bridge strip: 4 x 90 mm (w x l) (+/-10%)
- Two pre-attached elasticated straps, fitting (i) around top of the head,(ii) around base of the head
- Colour: white
- Non-sterile
- Single use, disposable
- Each mask bears clear identification of
  - o protection provided FFP2/N95,
  - o which side to wear up (nose),
  - o manufacturer's name, and
  - o model reference

### 5- Goggles, protective, indirect-side-ventilation

#### Technical specifications:

- Encloses a wide area surrounding the eyes
- Size: approx. 16 x 8 x 8 cm (w x h x d)
- Material, frame: translucent soft PVC
- Indirect ventilation channels (preventing penetration of splashes), one through each side of the frame
- Diameter of each vent, at least: 20mm
- Wrap-around adjustable elasticated headband, integrated with goggles frame
- Headband: approx. 30 x 1.5 cm (l x w)
- Material, lens part: polycarbonate, thickness 1 mm
- Lens is anti-fog treated/coated