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/cm2
• 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 H2O
- 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 bares clear identification of  
  - protection provided FFP2/N95,
  - which side to wear up (nose),
  - manufacturer's name, and
  - 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