

| ITB 6/2021 - Annex B - Lot 1,2 & 3 specifications | | | |
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| Lot # | Item Description | Technical specifications and description | Documentation to be submitted by the Supplier |
| Lot 1 | Gloves, examination, non-sterile, disp. - S | Gloves, examination, nitrile powder-free, non-sterile, single-use. Gloves should have long cuffs, reaching well above the wrist, ideally to mid-forearm. Sizes: small, medium, large <ul style="list-style-type: none"> • EU MDD Directive 93/42/EEC Category III • EU PPE Regulation 2016/425 Category III • EN 455 • EN 374 • ANSI/ISEA 105, • ASTM D6319, or equivalent set of standards | Brochures with photos, and technical and performance specifications. Confirmation on conformity to EN-455 and EN 374 |
| | Gloves, examination, non-sterile, disp. - M | | Confirmation ISO 9001 or 13485 certificate for Quality Management System of the manufacturer. Covering design, development, production and quality assurance of the device. |
| | Gloves, examination, non-sterile, disp. - L | | Test reports (product specific, from accredited laboratory/ test centre) Certificate of Origin |
| Lot 2 | Surgical mask- healthcare worker | Medical/surgical mask, high fluid resistance, good breathability, internal and external faces should be clearly identified, structured design that does not collapse against the mouth (e.g. duckbill, cup shaped) Technical specifications <ul style="list-style-type: none"> • 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 • 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 recognised marketing clearance) • In specific, compliant with the EN 14683 standard for type IIR (or equivalent international standard) EN 14683 Type IIR performance ASTM F2100 level 2 or level 3 or equivalent; Fluid resistance at minimum 120 mmHg pressure based on ASTM F1862-07, ISO 22609, or equivalent Breathability: MIL-M-36945C, EN 14683 annex C, or equivalent Filtration efficiency: ASTM F2101, EN14683 annex B, or equivalent | Brochures with photos, and technical and performance specifications. Confirmation of compliance with the EN 14683 standard for type IIR (or equivalent international standard) ISO or CE certificate |
| Lot 3 | Hand sanitizer | Capacity: 1 litre Minimum 70% alcohol Moisturizing Consistency: Gel With pumping mechanism | |
| | Medical examination gloves size S, M, L | Same as Lot 1 | Same as Lot 1 |
| | Surgical mask- healthcare worker | Same as Lot 2 | Same as Lot 2 |
| Lot 4 | Respiratory mask, N95 size S, M | N95 or FFP2 respirator, or higher. Good breathability with design that does not collapse against the mouth (e.g. duckbill, cup-shaped). General Description: Respirator mask protecting against airborne pathogens. Anti-penetration high filtration mask Technical specifications <ul style="list-style-type: none"> • 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 • With or without valve • 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: <ul style="list-style-type: none"> o protection provided FFP2/N95, o which side to wear up (nose), o manufacturer's name, and o model reference Respirator mask conforms to standards: NIOSH N95 recommended by the CDC and WHO for healthcare workers. The disposable respirator should be marked with the manufacturer's name, the part number (P/N), the protection provided by the filter (e.g. N-95) and "NIOSH." Or EN 149: 2001/FFP2. The disposable respirator should be marked with the manufacturer's name, EN 149: 2001/FFP2 and CE certification number. | Brochures with photos, and technical and performance specifications. Confirmation of compliance with the EN 149 or NIOSH 95 standard (or equivalent international standard) ISO 9001 or 13485 certificate for Quality Management System of the manufacturer. Covering design, development, production and quality assurance of the device. Certificate of Origin. ISO certificate |
| | Gown disposable, fluid penetration resistant, mid-calf length | General description: Gown, surgical, non-sterile, non-woven, disposable, Technical Specifications: <ul style="list-style-type: none"> • Surgical gown, with long sleeves, and a waist tie that binds at the side • Fabric, non-woven material. f.e. SMS, SMSMS, etc. • Outer layer liquid penetration resistant in critical areas (chest and sleeves) • Length (measured at front from middle of neckline to bottom): 130 – 145 cm • Circumference (measured at waist): 135–146 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: L, XL Conform requirements of: (a) EU Medical Devices Directive 93/42, Class I or (b) US FDA 510(k) clearance, Class II or (c) Equivalent internationally recognised marketing clearance In specific, compliant with: (a) EN 13795 standard (in the standard or high performance category) or (b) ANSI/AAMI PB70:2012 standard (in the AAMI Level 2 or higher) or (c) Equivalent international standard | Brochures with photos, and technical and performance specifications. ISO certificate Test reports (product specific, from accredited laboratory/ test centre) CE certificate (or equivalent) Certificate of Origin |