ANEXOS ESPECIFICACIONES TECNICAS

RFQ Nº UNFPA/DOM/RFQ/20/003

item	Product	Picture	WHO- 12 recommended items?	Specifications (as requested by MOH)	UoM	Quantity
1	Gloves, examination, long cuff, nitrile, powder free, non-sterile (Guantes, examen, puño largo, nitrato, sin polvo, no estéril (pares))		YES	Product description: Long-cuffed glove for clinical examinations and routine clinical laboratory work. Contains 5 fingers, palm and a sleeve. Disposable, non-powdered and non-sterile nitrile gloves are used to protect both patient, staff and environment from cross-contamination after handling infectious substances. Gloves should have long cuffs, reaching well above the wrist, ideally to mid-forearm. Technical Specifications: Fits either hand (ambidextrous shape). Material: 100% Nitrile. Powder free (non-powdered). Waterproof. Non-sterile. Single-use, disposable. Sizes available: S, M, L and XL. Size Medium dimensions: Total length: minimum 280mm. Width: 95 mm, +/- 10mm. Thickness: fingers:approx. 0.12mm; palm: 0.8mm Conformity requirements (WHO): • EU MDD Directive 93/42/EEC Class I or IIa, • EU PPE Regulation 2016/425 Category III, • EN 455, • EN 374, • ANSI/ISEA 105, • ASTM D6319, or equivalent set of standards Intended use: Strictly single use. A non-powdered glove, allowing the use of hydroalcoholic solution as hand cleanser. Wash hands before and after use of gloves. To be worn only on dry hands. Once removed, the gloves should be disposed of according to waste management rules. Never reuse. Store below 30°C protected from sunlight, heat and humidity. Packaging and labelling: Unit presentation: Hundred (100) gloves per box (50 pairs). Symbols used according ISO 15223. CE Mark. Manufacturer name and address. Lot/batch information. Must have words "non-powdered", or equivalent. Must indicate compliance to PPE 2016/425 Category III. Must indicate 'non-sterile, single use'. Must indicate 'latex free'	Box 50 pairs	2,115
2	Coverall, disposable (Overall, desechable)		YES	General description: Spray/aerosol-penetration resistant, biohazard-protective coverall, for use in EVD patient-isolation units for infection prevention and control against viral penetration. Personal protective equipment (non-hooded) that fully covers the wearer's body from neck to ankles. Intended to be worn over a surgical tunic and trousers to protect medical and non-medical staff from exposure to inorganic chemicals and infective biological agents. Protective clothing (PPE) category III complex design: Chemical protective clothing types 3, 4. Protective clothing against infective agents. Technical specifications: Elasticated hood around face. Elasticated cuffs and ankles. Sleeves with elasticated thumb loop. Protective seams providing barrier equal to fabric. Zipper with re-sealable flap protecting leakage through seams. Each coverall has a stitched-in neck label indicating the type and performance of the suit against the below mentioned standards. Color: White/ yellow/orange Material: Lightweight, do not contain rubber/ latex. Antistatic treated on both sides. Fabric is Infective agent tested against viral penetration at minimum 1.75kPa (minimum class 2, or equivalent standard). Non-sterile Single Use, disposable Intended use: Disposable liquid-tight biohazard-protective coverall, for use in EVD patient-isolation units for infection prevention and control against viral penetration. After use, the coverall must be disposed of in a biohazard waste container, collected and destroyed. This is also applicable if the coverall is damaged (perforation, etc.). Please refer to WHO publication "Safe management of waste for Health Care". Packaging and labelling: Packaging: One (1) unit in a plastic bag. Labelling on primary packaging (one unit) must include: - Name and/or trademark of the manufacturer - Manufacturer address - Manufacturer's product reference (product code) - Type of product and main characteristics - If the packaging is not transparent, it must bear a diagram showing the essential parts of the product - Information for particular storage conditions (temperature, pressure, light, humidity, etc.), as appropriate (or equivalent harmonised symbol) - Information for handling, if applicable (or equivalent harmonised symbol) - Words 'Non-sterile, disposable, single use' - CE mark (+ EC REP), FDA, and equivalent Meets the following european standards requirements: EU MDD directive 93/42/EEC EU PPE Regulation 2016/425 Category III EN 13034 : 2005 : Performance requirements for chemical protective clothing offering limited protective performance against liquid chemicals (type 6 clothing) EN 340: 2003 Protective clothing, general requirements EN 368/EN ISO 6530: resistance of materials to penetration by chemicals liquid en 14126: 2005. Protection against infective agents from risk groups 1,2,3,4 ISO 16603 : Determination of the resistance of protective clothing materials to penetration by blood and body fluids, test method using synthetic, under hydrostatic = 20 kPa - class 6/6 ISO 16604 : Determination of resistance of protective clothing materials to penetration by blood-borne pathogens, test method using Phi-X 174 bacteriophage, under hydrostatic = 20 kPa - class 6/6 ISO 22612 : test method for resistance to dry microbial (bacteria) penetration = log cfu ≤ 1 - classe 3 ISO 22611 : test method for resistance to penetration by biologically contaminated aerosols, using Staphylococcus aureus = log ratio >5 - class 3/3 ISO 22610 : test method to determine the resistance to wet bacterial penetration, when subjected to mechanical rubbing = > 75 min – classe 6/6 EN 14325 : 2004 : test methods and performance classification of chemical protective clothing materials, seams, joins and assemblages (abrasion resistance: >2000 cycles/class 6 of 6; Flex cracking resistance: >100 000 cycles/class 6 of 6; trapezoidal tear resistance: at least class 3 of 6; tensile strength (max. tear): class 2 of 6; Puncture resistance: class 2 of 6; resistance to ignition: at least class 1 of 3). en 1073-2 : 2002 : requirements and test methods for non-ventilated protective clothing against particulate radioactive contamination = class 1/3	Each	1,200

3	Surgical Respirator FFP2/N95, mask, disposable (Máscara quirúrgica FFP2/N95, desechable)		YES	"General Description: Respirator mask protecting against airborne pathogens. For medical use. Anti-penetration high filtration mask. Filtering device covering nose, mouth and chin, used to protect the wearer against airborne or droplets transmitted infectious agents. Filtering half mask: the face piece consists entirely or substantially of filter material or comprises a face piece in which the main filter(s) form an inseparable part of the device. Technical specifications: Material: non-woven filter layer. Polypropylene, polyester, polyethylene, aluminum. Meets the requirements of FFP2 or N95 (FFP2 or N95 must be written on the respirator itself). Filtration level: > 95 % for particles from 0.1 to 0.3 micron. Total inward leakage (TIL): <10% (N95) or <8% (FFP2). Penetration of the filtering material < 6% (NaCl and paraffine at 95 l/min with particles of 0.6 µm). Air permeability: > 2 mm H2O Meets the requirements of type IIR: Bacterial filtration efficiency (BFE) > or = 98%. Differential pressure (breathability) < 49 Pa. Splash resistance pressure > or = 120 mm hg (tested in accordance with ASTM F1862 standard). Shape of the mask: duckbill (folded horizontal width-wise), or cup-shaped. Good breathability with design that does not collapse against the mouth. 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, strong elastic straps, fitting (i) around top of the head, (ii) around base of the head. Color: white. Non-sterile. Single use, disposable. Each mask bares clear identification of (i) protection provided FFP2/N95, (ii) which side to wear up (nose), (iii) manufacturer's name, and (iv) model reference Conformity requirements (WHO): • Minimum ""N95"" respirator according to FDA Class II, under 21 CFR 878.4040, and CDC U.S. NIOSH, or • Minimum ""FFP2"" according to EN 149, EU PPE Regulation 2016/425 Category III, or equivalent • EN 14683:2014 ""Surgical masks - requirements and test methods"" Respirator with words "For occupational use" shall NOT be approved as this type is for construction and other industrial type jobs. CDC List of approved suppliers: https://www.cdc.gov/niosh/npptl/topics/respirators/disp_part/N95list1sect3.html Intended use: Respirator mask protecting against airborne pathogens. For medical use. Respirator offers a valuable security ONLY if: a) the size and the model are adapted to the wearer's face; b) the respirator is worn and used correctly by the wearer; c) a seal check is performed by the wearer before each exposure. First time users should CHECK THE MASK PERFORMANCE with a Fit Test Kit. Everytime a respirator is put on, PERFORM A SEAL CHECK. Check that the shelf life has not exceeded 5 years. If there is no marking for expiry date, check the elasticity of the straps before putting on. All damaged, wet or dirty respirators should be immediately discarded and replaced. Store in a dry and well-ventilated place. Packaging and labelling: Packaging: One (1) unit in a protective packaging. Manufacturer name and address. ISO 15223 CE mark (+EC REP), FDA and equivalent. Lot/batch, MFD and expiry date. Word 'non-sterile, single use, disposable.' Comes with instructions for use"	Box of 50 units	35
4	Surgical Mask, type IIR, for healthcare workers, disposable (mascarilla quirúrgica IIR, desechable)		YES	"General description: Mask, surgical, type IIR, tie strap or ear loops, disposable. Medical mask covering the nose, mouth and chin, designed to limit transmission of infectious agents exhaled by the nose and mouth of the wearer, and additionally to protect the wearer against liquid splashes. Technical specifications: . Splash resistant, type IIR or higher (EN 14683) surgical mask. . Bacterial filtering efficiency (BFE): equal to or greater than 98%. . Differential pressure (breathability)/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, e.g. polyethylene. . Comprised of 3 or 4 non-woven folded layers, shape completely covering nose, mouth and chin. . Clearly identifiable inner and outer surfaces. . Malleable nose strip, made of aluminum, allowing a snug fit. . With attached 2 x 2 tie-straps, allowing correct fixation and securing at the back of the head, or ear loops. . Size (indicative): 15-19 cm x 9-11 cm (l x w). Unfolded 175 x 175 mm. . Latex-free, glass fibre-free . Non-sterile . Single use, disposable Conformity requirements (WHO): • EU MDD directive 93/42/EEC Class I, or equivalent, • EN 14683 Type IIR (Type II or higher is acceptable). • ASTM F2100 minimum level 1 or equivalent. • ASTM F1862 splash resistance. Intended use: Worn by the medical staff, healthcare workers or support staff of the clinic. The surgical mask prevents the contamination spread to the people surrounding and the environment (air, surface, products…) around the wearer, and protects the wearer against liquid splashes. Safety instructions: Caution! A surgical mask does not protect the wearer against airborne infectious agents (coronavirus, TB, viral haemorrhagic fever, measles, varicella, SARS, avian influenza, etc.). In such cases, it is advisable to wear a surgical respirator, a protective mask rated at minimum FFP2 (complies with European standards) or N95 (complies with American standards). Not for reuse after removing from the face. The mask is to be replaced at least every 3 hours. Appropriate hand hygiene is to be applied before fitting and after removing the mask. Packaging and labelling: Packaging: Multiple units (50) per box. Manufacturer name and/or trademark, and address. Manufacturer's product reference. ISO 15223 CE mark (+EC REP), FDA and equivalent. Lot/batch, MFD and expiry date. Word 'non-sterile, single use, disposable.' Comes with instructions for use. Type IIR (EN 14683) is indicated. Information for particular storage conditions (temperature, pressure, light, humidity, etc.), as appropriate. Information for handling, if applicable (or equivalent harmonised symbol)."	Box of 50 units	800
5	Face Shield. Reusable (Protector facial, reutilizable)		YES	"Face Shield, reusable General Description: Durable full face length safety shield, fog-resistant. Encloses a wide area of the face ear-to-ear and forehead to chin. Can be worn with glasses or goggles, and with a N95 type respirator. Technical specifications: Durable full face length safety shield, fog-resistant. Encloses a wide area of the face ear-to-ear and forehead to chin. Can be worn with glasses or goggles. Made of clear plastic and provides good visibility to both the wearer and the patient. Material, shield part: clear polycarbonate, thickness approx. 1 mm. Made of robust material which can be cleaned and disinfected	each	800

				Made of robust material which can be cleaned and disinfected. Impermeable to liquids. Antistatic. Flexible. Size shield, from headband down approx.: 25 x 30 cm (w x h) Adjustable length headband, integrated with the shield. Adjustable band to attach firmly around the head and fit snuggly against the forehead. Width headband, approx.: 3 cm Front part of the headband is foam padded (length approx. 25 cm) Shield is anti-fog treated/coated (preferred). Outside is coated to prevent glare from reflection. Non sterile. Reusable. Conformity requirements (WHO): • EU PPE Regulation 2016/425, • EN 166, • ANSI/ISEA Z87.1, or equivalent set of standards Packaging and labelling: Packaging: One (1) unit in a protective packaging. Manufacturer name and address. ISO 15223 CE mark (+EC REP), FDA and equivalent. Lot/batch, MFD and expiry date. Word 'non-sterile, single use, disposable.' Comes with instructions for use, cleaning, decontamination from viral agents."		
6	Gown, isolation, non-woven, disposable (Bata de aislamiento, no tejido, desechable)		YES	General description: Non-sterile single use garment intended to be worn by healthcare providers or visitors to protect the patient from the transfer of infectious agents. It may also help to protect the healthcare provider or visitor from a contagious agent which has infected the patient. Technical specifications: Isolation gown (opening at the back), with long sleeves, a waist tie that binds at the back or front. Non-woven material, e.g. SMS, SMMS, polyethylene-coated polypropylene. Outer layer liquid penetration resistant in critical areas (full front and arms). Impermeable but breathable, flexible. Minimum average material density: 30 g/m2 Length (measured at front from middle of neckline to bottom): 110 – 150 cm (length mid-calf). Universal size but coverage of the whole upper body till under the knees is required. Width or circumference (measured at waist): minimum of 130 cm. Sleeves finished with double layer cuff, cotton or synthetic, stretchy (elastic) interlocked jersey band, length: 4 - 8 cm. Non-sterile. Single use, disposable. Conformity requirements (WHO): • EU PPE Regulation 2016/425 and EU MDD directive 93/42/EEC • FDA class I or II medical device, or equivalent; • EN 13795 any performance level, or • AAMI PB70 all levels acceptable, or equivalent Intended use: To be worn when there is a protection isolation of an immune-depressed patient; or an infectious isolation: contagious diseases transmitting by airborne contact (droplets). Follow the infection control rules of undressing and dressing. Packaging and labelling: Packaging: One (1) unit in a plastic bag. Labelling on primary packaging (one unit) must include: - Name and/or trademark of the manufacturer - Manufacturer address - Manufacturer's product reference (product code) - Type of product and main characteristics - If the packaging is not transparent, it must bear a diagram showing the essential parts of the product - Information for particular storage conditions (temperature, pressure, light, humidity, etc.), as appropriate (or equivalent harmonised symbol) - Information for handling, if applicable (or equivalent harmonised symbol) - Words 'Non-sterile, disposable, single use' - Word 'Universal size' - CE mark (+ EC REP), FDA, and equivalent Secondary packaging: Packaging of multiple units Labelling to be the same as primary packaging. Extra information required: Number of units per box	Each	7,450
7	Gloves, surgical, long cuff, nitrile, powder free, sterile (Guantes quirúrgicos, puño largo, nitrato, sin polvo, estériles (pares))		YES	Product description: Glove for clinical and surgical procedures. Contains 5 fingers, palm and a long sleeve. Disposable, non-powdered and sterile nitrile long cuff gloves are used to protect both patient, staff and environment from infectious substances. Gloves should have long cuffs, reaching well above the wrist, ideally to mid-forearm. Technical Specifications: Fits either hand (ambidextrous shape). Material: 100% Nitrile. Powder free (non-powdered). Long sleeve (long cuff). Waterproof. Sterile. Single-use, disposable. Sizes ranging from 5.0 to 9.0 (or S, M, L, XL) Size 7.0 dimensions: Total length: minimum 280mm. Width: 89 mm, +/- 5mm. Thickness: fingers:approx. 0.12mm; palm: 0.8mm. Size Medium dimensions: Total length: minimum 280mm. Width: 95 mm, +/- 10mm. Thickness: fingers:approx. 0.12mm; palm: 0.8mm. Conformity requirements (WHO): • EU MDD Directive 93/42/EEC Class IIa, • EU PPE Regulation 2016/425 Category III, • EN 455, • ANSI/ISEA 105, • ASTM D6319, or equivalent set of standards Intended use: Strictly single use. A non-powdered glove, allowing the use of hydroalcoholic solution as hand cleanser. Wash hands before and after use of gloves. To be worn only on dry hands. Once removed, the gloves should be disposed of according to waste management rules. Never reuse. Store below 30°C protected from sunlight, heat and humidity. Packaging and labelling: Unit presentation: One (1) pair in peel-open pack. Symbols used according ISO 15223. CE Mark. Manufacturer name and address. Lot/batch and Expiry information. Must have words "non-powdered", or equivalent. Must indicate compliance to PPE 2016/425 Category III. Must indicate 'sterile, single use'. Must indicate 'latex free'.	Box 50 pairs	290
8	Surgical Mask, type I, for patients, disposable (Mascarilla Quirúrgica, tipo I, desechable)		YES	Surgical Mask, type I, for patients, non-sterile, disposable General description: Disposable surgical (or medical) mask, type I, for patients suspected or confirmed viral infection. Medical mask covering the nose, mouth and chin, designed to limit transmission of infectious agents exhaled by the nose and mouth of the patient. This mask (type I) is not intended for protection of the wearer from the viral infection (Note: this mask is NOT to be used by the healthcare workers). Technical specifications: . Type I (EN 14683) surgical or medical mask. . Bacterial filtering efficiency (BFE): equal to or greater than 95%. . Differential pressure (breathability)/Breathing resistance: equal to or less than 29.4 Pa/cm2. . Splash resistance: None. . Fabric, non-woven with outer layer impervious liquid splash resistant material, e.g. polyethylene. . Comprised of 3 non-woven folded layers, shape completely covering nose, mouth and chin. . Clearly identifiable inner and outer surfaces. . Malleable nose strip, made of aluminum, allowing a snug fit. . With attached 2 x 2 tie-straps, allowing correct fixation and securing at the back of the head, or ear loops. . Size (indicative): 15-19 cm x 9-11 cm (l x w). Unfolded 175 x 175 mm. . Latex-free, glass fibre-free . Non-sterile . Single use, disposable Conformity requirements (WHO): • EU MDD directive 93/42/EEC Class I, or equivalent. • EN 14683 Type I	Box of 50	25

				• EN 14683 Type I • ASTM F2100 minimum level 1 or equivalent. Intended use: Worn by the contagious patient, suspected or verified COVID-19 patients. The surgical mask prevents the contamination spread to the people surrounding and the environment (air, surface, products…) around the wearer because the mask captures liquid droplets from the nose and mouth of the wearer. Safety instructions: Caution! This mask does not protect the wearer against liquid splashes, and it is not designed to prevent getting infected. Note! A surgical or medical mask does not protect the wearer against airborne infectious agents (coronavirus, TB, viral haemorrhagic fever, measles, varicella, SARS, avian influenza, etc.). Not for reuse after removing from the face. The mask is to be replaced at least every 3 hours. Appropriate hand hygiene is to be applied before fitting and after removing the mask. Packaging and labelling: Packaging: Multiple units (50) per box. Manufacturer name and/or trademark, and address. Manufacturer's product reference. ISO 15223 CE mark (+EC REP), FDA and equivalent. Lot/batch, MFD and expiry date. Word 'non-sterile, single use, disposable.' Comes with instructions for use. Type I (EN 14683) is indicated. Information for particular storage conditions (temperature, pressure, light, humidity, etc.), as appropriate. Information for handling, if applicable (or equivalent harmonised symbol).		
9	Head cover, waterproof, disposable, non-sterile (Gorro quirúrgico, a prueba de agua, desechable, no sterile)		YES	Head cover, waterproof, disposable, non-sterile General Description: A non-sterile head covering designed as a cap to completely cover the hair and is intended to be worn by surgical staff during an operation to protect both the patient and themselves from the transfer of microorganisms, body fluids, and particulate material. It is an elasticated cap made of non-woven materials. Technical specifications: Non-woven (polypropylene, viscose, etc.) Non-permeable to liquid. Waterproof. For medical use. Weight: 10 to 30 g/m2 (e.g. cap of 6 g = 28 g/m2). Elastic opening permitting complete coverage of all hairstyles (Ø ± 50 cm). Latex-free. One-size-fits-all. Non sterile, single use. Intended use: It is mandatory for all operating theatre staff to wear a surgical cap. Non-woven surgical caps are intended for situations where sterilization is problematic. Dispose after use. Conformity requirements: • EU PPE Regulation 2016/425, • EU MDD Directive 93/42/EEC • EN 343 for water and breathability or equivalent Packaging: One (1) unit in a protective packaging. Alternatively multiple units per box (20 to 50). Manufacturer name and address. ISO 15223. CE mark (+EC REP), FDA and equivalent. Lot/batch, MFD and expiry date. Word 'non-sterile, single use, disposable.'	Box of 100	285
10	Goggle, panoramic, regular nose, indirect ventilation (Gafas, panorámicas, nariz regular, ventilación indirecta, reutilizables)		YES	General Description: Goggle, panoramic, regular nose, indirect ventilation. Goggles, or safety glasses, are forms of protective eyewear that usually enclose or protect the area surrounding the eye in order to prevent particulates, water or chemicals from striking the eyes. In haemorrhagic fever contexts it is recommended to use safety wrap around goggles: they protect the eyes from dust and splashing. Technical specifications: Good seal with the skin of the face. Reusable. Markings written on the goggles (frame and lenses) according to the EN 166 specifications: Mechanical class = F = Minimum mechanical resistance (resistance to shocks of low-energy particles): withstands a bead of 6 mm and 0.85 g at 45m/s impact. Optic class 1 or 2 = applicable for intermittent use, for activities with medium visual requirements. K = Anti-Scratch N = Anti-Fog Frame Protection class = 3 Protection against liquid doplets.	Each	120