

Technical Specifications for Health Supplies – COVID-19

Invitation to Bid (ITB) UNFPA/PER/ No.002-2020

1. Purpose of the purchase

Acquisition of Protective Equipment (PPE) in the framework of the health emergency caused by COVID-19.

2. Scope and description of the goods to be acquired


The items to be acquired must meet the required specifications and guarantee the quality and efficiency of their action in fulfilling the purpose for which they are acquired, according to the needs of our institution.

ÍTEM	DESCRIPTION	QUANTITY	UNIT OF MEASURE
1	SURGICAL RESPIRATOR FFP2/N95, MASK, DISPOSABLE	800 Boxes	Box (50 units)
2	GLOVES, EXAMINATION, LONG CUFF, NITRILE, POWDER FREE, NON-STERILE *The box quantity requirement per size are specified in the technical specification document	15000 Boxes	Box 50 pairs (100 units)
3	SURGICAL MASK, TYPE IIR, FOR HEALTHCARE WORKERS, DISPOSABLE	5000 Boxes	Box (50 units)
4	GLOVES, SURGICAL, LONG CUFF, NITRILE, POWDER FREE, STERILE *The box quantity requirement per size are specified in the technical specification document	1798 Boxes	Box 50 pairs (100 units)
5	COVERALL, DISPOSABLE *The quantity requirement per size are specified in the technical specification document	7000 units	Unit
6	SURGICAL MASK, TYPE I, FOR PATIENTS, DISPOSABLE	10000 Boxes	Box (50 units)


3. Minimum Requirements


ÍTEM	DESCRIPCIÓN
1	<p>SURGICAL RESPIRATOR FFP2/N95, MASK, DISPOSABLE</p> <p><u>General Description</u> 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.</p> <p><u>Technical specifications</u> 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.</p>




	<p>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</p> <p>Conformity requirements (WHO):</p> <ul style="list-style-type: none"> • 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" <p>Note:</p> <ul style="list-style-type: none"> • You must indicate as part of your technical offer, what type of mask is the one you offer. • You must attach as part of your technical offer, the technical sheet of the product in which it is stated at least: <ul style="list-style-type: none"> - Packaging and labelling information: 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.
2	<p>GLOVES, EXAMINATION, LONG CUFF, NITRILE, POWDER FREE, NON-STERILE</p>
	<p><u>Product description:</u> 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.</p>

	<p><u>Technical Specifications:</u> 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.</p> <p>Requirement:</p> <p>3000 size S boxes 5250 size M boxes 5250 size L boxes 1500 size XL boxes</p> <p>Size Medium dimensions: Total length: minimum 280mm. Width: 95 mm, +/- 10mm. Thickness: fingers: approx. 0.12mm; palm: 0.8mm.</p> <p>Conformity requirements (WHO):</p> <ul style="list-style-type: none"> • 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 <p>Note:</p> <ul style="list-style-type: none"> • You must attach as part of your technical offer, the technical sheet of the product in which it is stated at least: <ul style="list-style-type: none"> - Packaging and labelling information 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'.
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	- Must indicate 'latex free'.
3	SURGICAL MASK, TYPE IIR, FOR HEALTHCARE WORKERS, DISPOSABLE
	<p><u>General description:</u> 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.</p> <p><u>Technical specifications:</u></p> <ul style="list-style-type: none"> . 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 <p><u>Conformity requirements (WHO):</u></p> <ul style="list-style-type: none"> • 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. <p>Note:</p> <ul style="list-style-type: none"> • You must attach as part of your technical offer, the technical sheet of the product in which it is stated at least:

	<ul style="list-style-type: none"> - Packaging and labelling information 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).
4	GLOVES, SURGICAL, LONG CUFF, NITRILE, POWDER FREE, STERILE
	<p><u>Product description:</u> 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.</p> <p><u>Technical Specifications:</u> 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)</p> <p>Requirement</p> <p>399 size S boxes 549 size M boxes 549 size L boxes 301 size XL boxes</p>

	<p>Size 7.0 dimensions: Total length: minimum 280mm. Width: 89 mm, +/- 5mm. Thickness: fingers:approx. 0.12mm; palm: 0.8mm.</p> <p>Size Medium dimensions: Total length: minimum 280mm. Width: 95 mm, +/- 10mm. Thickness: fingers:approx. 0.12mm; palm: 0.8mm.</p> <p>Conformity requirements (WHO):</p> <ul style="list-style-type: none"> • 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 <p>Note:</p> <ul style="list-style-type: none"> • You must attach as part of your technical offer, the technical sheet of the product in which it is stated at least: <p>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'.</p>
5	COVERALL, DISPOSABLE
	<p>Coverall, protection, Category III, type 6b (particle tight, limited splash-proof) Coverall, protection, Category III, type 5b (particle tight, limited splash-proof) Coverall, protection, Category III, type 4b (spray tight) Coverall, protection, Category III, type 3b (liquid tight)</p> <p><u>General description:</u> 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</p>

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

Several sizes:




	H		C	
S	64-67in	164 - 170cm	33-36in	84 - 92cm
M	66-69in	167 - 176cm	36-39in	92 - 100cm
L	69-71in	174 - 181cm	39-43in	100 - 108cm
XL	70-74in	179 - 187cm	43-45in	108 - 115cm
2XL	73-76in	186 - 194cm	45-49in	115 - 124cm
3XL	76-78in	194 - 200cm	49-52in	124 - 132cm
4XL	78-81in	200 - 206cm	52-55in	132 - 140cm

Requirement

1400 size S units

3150 size M units

	<p>2450 size L units</p> <p>Note</p> <ul style="list-style-type: none"> You must attach as part of your technical offer, the technical sheet of the product in which it is stated at least: <ul style="list-style-type: none"> Packaging and labelling information: Packaging: One (1) unit in a plastic bag. Labelling on primary packaging (one unit) must include: <ul style="list-style-type: none"> 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 <p>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</p>
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	<p>(bacteria) penetration = $\log \text{cfu} \leq 1$ - classe 3</p> <p>ISO 22611 : test method for resistance to penetration by biologically contaminated aerosols, using Staphylococcus aureus = $\log \text{ratio} > 5$ - class 3/3</p> <p>ISO 22610 : test method to determine the resistance to wet bacterial penetration, when subjected to mechanical rubbing = $> 75 \text{ min}$ – classe 6/6</p> <p>EN 14325 : 2004 : test methods and performance classification of chemical protective clothing materials, seams, joins and assemblages (abrasion resistance: $> 2000 \text{ cycles/class 6 of 6}$; Flex cracking resistance: $> 100\,000 \text{ cycles/class 6 of 6}$; 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).</p> <p>en 1073-2 : 2002 : requirements and test methods for non-ventilated protective clothing against particulate radioactive contamination = class 1/3</p> <p>EN 1149-5 & en 1149-1 : electrostatic properties = class 2</p> <p>eEN ISO 13935-2 : 2004 : Determination of maximum force to seam rupture using the grab method = $> 125 \text{ n}$, level 4/6</p> <p>ISO 17491-3 : 2008 : test methods for clothing providing protection against chemicals - Part 3: Determination of resistance to penetration by a jet of liquid (jet test)</p> <p>ISO 17491-4 : 2008 : test methods for clothing providing protection against chemicals - Part 4: Determination of resistance to penetration by a spray of liquid (spray test)</p> <p>EN ISO 13982-1 : 2004 : Performance requirements for chemical protective clothing providing protection to the full body against airborne solid particulates (type 5 clothing)</p> <p>Performance requirement ISO standards:</p> <p>ISO 3758 – Textile care symbols</p> <p>EN 12941 – Respiratory protective devices – Powered filtering devices</p> <p>EN 31092 – Determination of physiological properties – thermal and water-vapour resistance</p>
6	<p>SURGICAL MASK, TYPE I, FOR PATIENTS, DISPOSABLE</p>
	<p><u>General description:</u></p> <p>Disposable surgical (or medical) mask, type I, for patients suspected or confirmed viral infection.</p> <p>Medical mask covering the nose, mouth and chin, designed to limit transmission of infectious agents exhaled by the nose and mouth of the patient.</p>

	<p>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).</p> <p>Technical specifications:</p> <ul style="list-style-type: none"> . 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 <p>Conformity requirements (WHO):</p> <ul style="list-style-type: none"> • EU MDD directive 93/42/EEC Class I, or equivalent. • EN 14683 Type I • ASTM F2100 minimum level 1 or equivalent. <p>Note:</p> <ul style="list-style-type: none"> • You must attach as part of your technical offer, the technical sheet of the product in which it is stated at least: <ul style="list-style-type: none"> - Packaging and labelling information: 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. - Type I (EN 14683) is indicated.
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	<ul style="list-style-type: none">- Information for particular storage conditions (temperature, pressure, light, humidity, etc.), as appropriate.- Information for handling, if applicable (or equivalent harmonised symbol).
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