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ANNEX B

TECHNICAL SPECIFICATIONS

#	Product		Intended use
	UNICEF Mat. No	Description	
10	S0305109	Mask, high-fil., FFP2/N-95, no-valve, none sterile	Healthcare workers/Front line COVD responders
20	S6780349	Mask,HighFill,FFP2/N95ValveNonsterBOX-10	Healthcare workers/Front line COVD responders
30	S0305086	Mask,high-fil,FFP3/N-100	Healthcare workers/Front line COVD responders
40	S0305135	Mask, surgical, type IIR, tie strap, disp./PAC50	Healthcare workers/ Patients without symptoms suggestive of COVID-19/ Caregiver
50	S0305146	Mask, medical, type I, disp/BOX-50	Frontline working for Essential services outside of COVID response
60	S6780363	Mask, surgic, typeII, disp., pack of 50	Frontline working for Essential services outside of COVID response
70	S0305117	Coverall, protection, Cat III, type 6b, L	Cleaners/ Ambulance
80	S0305126	Coverall, protection, Cat III, type 6b, M	Cleaners/ Ambulance
90	S0305127	Coverall, protection, Cat III, type 6b, XL	Cleaners/ Ambulance
100	S0305144	Goggles, protective, indirect-side-ventil	Healthcare workers/Cleaners
110	S0969026	Gloves, w/o powder, nitrile, L, disp./BOX-100	Healthcare workers
120	S0969025	Gloves, w/o powder, nitrile, M, disp./BOX-100	Healthcare workers
130	S0305138	Gown, surgical, non-sterile, non-woven, disp., L	Healthcare workers
140	S0305140	Gown, surgical, non-sterile, non-woven, disp., XL	Healthcare workers
150	S0305139	Gown,isol,nonwoven,ligt,ISO16604,disp,XL	Healthcare workers
160	S0305136	Gown, isolation, nonwoven,disp,pack10	Healthcare workers
170	S0305137	Gown, isol,nonwoven,ligt,ISO16604,disp,L	Healthcare workers
180	S0305078	Cap, surgical, bouffant, non-woven	Healthcare workers
190	S0305131	HE Apron,protect,plastic,disp/PAC-100	Cleaners
200	S0305129	Boot covers	Cleaners
210	S0305116	Faceshield,fog-resistant,fullface,disp	Healthcare workers/Cleaners
220	U282700	PPE	For submitting alternative offers for any of the above products

S0305109 Mask,high-fil,FFP2/N95,no valve,nonster

Intended use:
Worn on the face and covers at least the nose and mouth. It is recommended for use to reduce the Healthcare worker's risk of inhaling hazardous airborne particles (including dust particles and infectious agents), gases, or vapors.

General Description:
Respirator mask protecting against airborne pathogens. Anti-penetration high filtration mask

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
- 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
    - protection provided FFP2/N95,
    - which side to wear up (nose),
    - manufacturer's name, and
    - 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.

Supplier to submit and inform with the offer:
(i) Product reference(s) of item(s) offered
(ii) Brochures with photos, and technical and performance specifications.
(iii) Copy of instructions for use in English, French and Spanish.
(iv) List of items required, but not supplied, if applicable.
(v) ISO 9001 or 13485 certificate for Quality Management System of the manufacturer. Covering design, development, production and quality assurance of the device.
(vi) Copy of a valid CE (EU) 2016/425 Category III (or equivalent) marketing approval certificate (see technical provision section)
(vii) Confirmation of compliance with the EN 149 or NIOSH 95 standard (or equivalent international standard)

S6780349 Mask,HighFill,FFP2/N95ValveNonsterBOX-10

Intended use:
Worn on the face and covers at least the nose and mouth. It is recommended for use to reduce the Healthcare worker's risk of inhaling hazardous airborne particles (including dust particles and infectious agents), gases, or vapors.

General Description:
Respirator mask protecting against airborne pathogens. Anti-penetration high filtration mask

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
- 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
    - protection provided FFP2/N95,
    - which side to wear up (nose),
    - manufacturer's name, and
    - 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.

Supplier to submit and inform with the offer:
(i) Product reference(s) of item(s) offered
(ii) Brochures with photos, and technical and performance specifications.
(iii) Copy of instructions for use in English, French and Spanish.
(iv) List of items required, but not supplied, if applicable.
(v) ISO 9001 or 13485 certificate for Quality Management System of the manufacturer. Covering design, development, production and quality assurance of the device.
(vi) Copy of a valid CE (EU) 2016/425 Category III (or equivalent) marketing approval certificate (see technical provision section)
(vii) Confirmation of compliance with the EN 149 or NIOSH 95 standard (or equivalent international standard)

S0305086 Mask,high-fil,FFP3/N-100

Intended use:
Worn on the face and covers at least the nose and mouth. It is recommended for use to reduce the Healthcare worker's risk of inhaling hazardous airborne particles (including dust particles and infectious agents), gases, or vapors.

General Description:
Mask,high-fil,FFP3/N-100

Technical Specifications:
- Respirator mask to protect against airborne infectious diseases
- Anti-discharge, anti-penetration, and high filtration mask
- Filtration level: > 99.7% for particles from 0.1 to 0.3 micron
- Air permeability: > 2mm H2O
- Respirator mask should fit a wide range of face shapes
- Contour design to ensure the compatibility of glasses/goggles and reduce fogging
- Regular size
- 2 Elastic loop or fully adjustable head straps (back of the head and neck)
- Malleable nose bridge
- Non-sterile
- Single-use
- Each mask bares clear identification of
    - protection provided FFP3,
    - which side to wear up (nose),
    - manufacturer's name, and
    - model reference

Respirator mask conforms to standards:
Respirator mask conforms to: NIOSH N100. The disposable respirator should be marked with the manufacturer's name, the part number (P/N), the protection provided by the filter (i.e. N-100), and "NIOSH."
Or
EN 149: 2001/FFP3 (in conformity with Regulation (EU) 2016/425).
The disposable respirator is marked with the manufacturer's name, EN149: 2001/FFP3 or N100 and CE certification number.

Supplier to submit and inform with the offer:
(i) Product reference(s) of item(s) offered
(ii) Brochures with photos, and technical and performance specifications.
(iii) Copy of instructions for use in English, French and Spanish.
(iv) List of items required, but not supplied, if applicable.
(v) ISO 9001 or 13485 certificate for Quality Management System of the manufacturer. Covering design, development, production and quality assurance of the device.
(vi) Copy of a valid CE (EU) 2016/425 Category III (or equivalent) marketing approval certificate (see technical provision section)
(vii) Confirmation of compliance with the EN 149 or NIOSH 100 standard (or equivalent international standard)

S0305135 Mask, surgical, type IIR, tie strap, disp./PAC50

Intended use:
Helps to prevent the respiratory secretions produced by the suspected patient and avoid contaminating other persons and surfaces.

General description:
Mask,surgic,typeIIR,tiestrap,disp., pack of 50

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
- 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)

Packaging and labelling:
Primary packaging 50 units

Labelling on primary packaging must include:
- Name and/or trademark of the manufacturer
- Manufacturer's product reference
- Type of product and main characteristics
- If the packaging is not transparent, it must bear a diagram (preferably actual size) showing the essential parts of the product and indicating the position of the product in the packaging
- 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)

Over packaging: Packaging unit
Labelling on the packaging unit: Labelling to be the same as primary packaging.
Extra information required: Number of units per box.

S0305146 Mask, medical, type I, disp/BOX-50

Intended use:
Helps to prevent the respiratory secretions and avoid contaminating other persons and surfaces.

General description:
Face mask for public use

Technical specifications:
- Type I mask
- Bacterial filtering efficiency: equal to or greater than 95%
- Fabric, non-woven
- 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

Packaging and labelling:
Primary packaging 50 units

Labelling on primary packaging must include:
- Name and/or trademark of the manufacturer
- Manufacturer's product reference
- Type of product and main characteristics
- If the packaging is not transparent, it must bear a diagram (preferably actual size) showing the essential parts of the product and indicating the position of the product in the packaging
- 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)

Over packaging: Packaging unit
Labelling on the packaging unit: Labelling to be the same as primary packaging.
Extra information required: Number of units per box.

S6780363 Mask,surgic,typeII,disp., pack of 50

Intended use:
Helps to prevent the respiratory secretions and avoid contaminating other persons and surfaces.

Technical specifications:
- Type II surgical mask
- Bacterial filtering efficiency: equal to or greater than 98%
- Breathing resistance: equal to or less than 29.4 Pa/cm2
- Fabric, non-woven, 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 II (or equivalent international standard)

Packaging and labelling:
Primary packaging 50 units

Labelling on primary packaging must include:
- Name and/or trademark of the manufacturer
- Manufacturer's product reference
- Type of product and main characteristics
- If the packaging is not transparent, it must bear a diagram (preferably actual size) showing the essential parts of the product and indicating the position of the product in the packaging
- 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)
Over packaging: Packaging unit
Labelling on the packaging unit: Labelling to be the same as primary packaging.
Extra information required: Number of units per box.

S0305117 Coverall, protection, Cat III, type 6b, L

Intended Use:
To protect skin and prevent soiling or contamination of clothing during procedures expected to have fluid that might penetrate the protective suite

General description:
Spray/aerosol-penetration resistant, biohazard-protective coverall, for use in isolation units for infection prevention and control against viral penetration.

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 minimum1.75kPa (class 2) (or equivalent international standard)
- Non-sterile
- Single Use, disposable
- Size: L

Conforms to:
European Regulation (EU) 2016/425 on personal protective equipment Category III: Chemical protective coverall, Type 6 comply with EN 13034:2005+A1 (or equivalent) marketing approval certificate.
Barrier to infective agent standards: EN 14126:2003 certified passing infectious agent test according to ISO 16604:2004 (Resistance to penetration by blood-borne pathogens using bacteriophage Phi-X 174) standard at minimum exposure pressure of 1.75kPa (class 2) (or equivalent international standard)

Performance requirement ISO standards:
EN 340 – General requirements
EN ISO 17491-4: 2008 (supersedes: EN 468 mod. – Spray aerosol test)
EN 14325 – Test methods & performance classification
EN ISO 3758 (ISO 3758) – Textile care symbols
EN ISO 13935-2 – Seam strength

Packaging: Individually packaged in a transparent plastic bag.

Labelling on the primary packaging:
Name and/or trademark of the manufacturer.
Manufacturer's product reference.
Type of product and main characteristics.
If the packaging is not transparent, it must bear a diagram (preferably actual size) showing the essential parts of the product and indicating the position of the product in the packaging.
Lot number prefixed by the word "LOT" (or equivalent harmonised symbol) (if applicable).

Expiry date by year and month, prefixed by the word "EXP" (or equivalent harmonised symbol) (if applicable).
The words "for single use" (or equivalent harmonised symbol).
The words "destroy after use" (if space allows).
Number of units per primary packaging (if applicable).
Information for particular storage conditions (temperature, pressure, light, humidity, etc.), as appropriate (or equivalent harmonised symbol).

Supplier to indicate, for 1 unit/set per primary packaging:
(i) Gross volume, primary packaging (in m3)
(ii) Gross weight, primary packaging (in kg)

Supplier to submit and inform with the offer:
(i) Product reference(s) of item(s) offered
(ii) Brochures with photos, and technical and performance specifications.
(iii) Copy of instruction for correct use, manual in English/French/Spanish
(iv) List of items required, but not supplied, if applicable.
(v) ISO 9001 or 13485 certificate for Quality Management System of the manufacturer. Covering design, development, production and quality assurance of the device. Kindly submit a readable copy of certificate, in English.
(vi) Copy of a valid CE (EU) 2016/425, Category III: Chemical protective coverall, Type 6 comply with EN 13034:2005 + A1:2009 (or equivalent) marketing approval certificate (see technical provision section).
(vii) Confirmation of compliance with the EN 14126:2003 passing infectious agent test according to ISO 16604:2004 standard at minimum exposure pressure of 1.75kPa (class 2) (or equivalent international standard)

S0305126 Coverall,protection,CatIII,type 6b,M

Intended Use:
To protect skin and prevent soiling or contamination of clothing during procedures expected to have fluid that might penetrate the protective suite

General description:
Spray/aerosol-penetration resistant, biohazard-protective coverall, for use in isolation units for infection prevention and control against viral penetration.

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

Conforms to:
European Regulation (EU) 2016/425 on personal protective equipment Category III: Chemical protective coverall, Type 6 comply with EN 13034:2005+A1 (or equivalent) marketing approval certificate.
Barrier to infective agent standards: EN 14126:2003 certified passing infectious agent test according to ISO 16604:2004 (Resistance to penetration by blood-borne pathogens using bacteriophage Phi-X 174) standard at minimum exposure pressure of 1.75kPa (class 2) (or equivalent international standard)

Performance requirement ISO standards:
EN 340 – General requirements
EN ISO 17491-4: 2008 (supersedes: EN 468 mod. – Spray aerosol test)
EN 14325 – Test methods & performance classification
EN ISO 3758 (ISO 3758) – Textile care symbols
EN ISO 13935-2 – Seam strength

Packaging: Individually packaged in a transparent plastic bag.

Labelling on the primary packaging:
Name and/or trademark of the manufacturer.
Manufacturer's product reference.
Type of product and main characteristics.
If the packaging is not transparent, it must bear a diagram (preferably actual size) showing the essential parts of the product and indicating the position of the product in the packaging.
Lot number prefixed by the word "LOT" (or equivalent harmonised symbol) (if applicable).

Expiry date by year and month, prefixed by the word "EXP" (or equivalent harmonised symbol) (if applicable).
The words "for single use" (or equivalent harmonised symbol).
The words "destroy after use" (if space allows).
Number of units per primary packaging (if applicable).
Information for particular storage conditions (temperature, pressure, light, humidity, etc.), as appropriate (or equivalent harmonised symbol).

Supplier to indicate, for 1 unit/set per primary packaging:
(i) Gross volume, primary packaging (in m3)
(ii) Gross weight, primary packaging (in kg)

Supplier to submit and inform with the offer:
(i) Product reference(s) of item(s) offered
(ii) Brochures with photos, and technical and performance specifications.
(iii) Copy of instruction for correct use, manual in English/French/Spanish
(iv) List of items required, but not supplied, if applicable.
(v) ISO 9001 or 13485 certificate for Quality Management System of the manufacturer. Covering design, development, production and quality assurance of the device. Kindly submit a readable copy of certificate, in English.
(vi) Copy of a valid CE (EU) 2016/425, Category III: Chemical protective coverall, Type 6 comply with EN 13034:2005 + A1:2009 (or equivalent) marketing approval certificate (see technical provision section).
(vii) Confirmation of compliance with the EN 14126:2003 passing infectious agent test according to ISO 16604:2004 standard at minimum exposure pressure of 1.75kPa (class 2) (or equivalent international standard)

S0305127 Coverall,protection,CatIII,type 6b,M

Intended Use:
To protect skin and prevent soiling or contamination of clothing during procedures expected to have fluid that might penetrate the protective suite.

General Description:
Spray/aerosol-penetration resistant, biohazard-protective coverall, for use in isolation units for infection prevention and control against viral penetration

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 minimum1.75kPa (class 2) (or equivalent international standard)
- Non-sterile
- Single Use, disposable
- Size: XL
- Primary packaging: Unit of use.
- One coverall and one product information technical datasheet co-packed in a plastic bag.

Conform to:
European Directive Regulation (EU) 2016/425 on personal protective equipment Category III: Chemical protective coverall, Type 6 comply with EN 13034:2005+A1(or equivalent) marketing approval certificate.
Barrier to infective agent standards: EN 14126:2003 certified passing infectious agent test according to ISO 16604:2004 (Resistance to penetration by blood-borne pathogens using bacteriophage Phi-X 174) standard at minimum exposure pressure of 1.75kPa (class 2) (or equivalent international standard)

Performance requirement ISO standards:
EN 340 – General requirements
EN ISO 17491-4: 2008 (supersedes: EN 468 mod. – Spray aerosol test)
EN 14325 – Test methods & performance classification
EN ISO 3758 (ISO 3758) – Textile care symbols
EN ISO 13935-2 – Seam strength

Labelling of the primary packaging displays,
Name and/or trademark of the manufacturer.
Manufacturer's product reference.

Type of product and main characteristics.
If the packaging is not transparent, it must bear a diagram (preferably actual size) showing the essential parts of the product and indicating the position of the product in the packaging.
Lot number prefixed by the word "LOT" (or equivalent harmonised symbol) (if applicable).
Expiry date by year and month, prefixed by the word "EXP" (or equivalent harmonised symbol) (if applicable).
The words "for single use" (or equivalent harmonised symbol).
The words "destroy after use" (if space allows).
Number of units per primary packaging (if applicable).
Information for particular storage conditions (temperature, pressure, light, humidity, etc.), as appropriate (or equivalent harmonised symbol).

Supplier to indicate, for 1 unit/set per primary packaging:
(i) Gross volume, primary packaging (in m3)
(ii) Gross weight, primary packaging (in kg)

Supplier to submit and inform with the offer:
(i) Product reference(s) of item(s) offered
(ii) Brochures with photos, and technical and performance specifications.
(iii) Copy of instruction for correct use, manual in English/French/Spanish
(iv) List of items required, but not supplied, if applicable.
(v) ISO 9001 or 13485 certificate for Quality Management System of the manufacturer. Covering design, development, production and quality assurance of the device. Kindly submit a readable copy of certificate,in English.
(vi) Copy of a valid CE (EU) 2016/425, Category III: Chemical protective coverall, Type 6 comply with EN 13034:2005 + A1:2009 (or equivalent) marketing approval certificate (see technical provision section)
(vii) Confirmation of compliance with the EN 14126:2003 passing infectious agent test according to ISO 16604:2004 standard at minimum exposure pressure of 1.75kPa (class 2) (or equivalent international standard)

S0305144 Goggles,protective,indirect-side-ventil

Intended Use:
Eye Protection. to avoid contamination of mucous membranes

General Description:
Durable safety goggles. Indirect-ventilation goggles feature an angled, vented portion that does not allow for direct, straight-line passage from the exterior to the interior of the eyewear.

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.

Standards:
Must meet ANSI Z87.1-2010 Standard or its update for Chemical Splash and Dust Protection.

Supplier to indicate, for 1 unit/set per primary packaging:
(i) Gross volume, primary packaging (in m3).
(ii) Gross weight, primary packaging (in kg).

Supplier to submit and inform with the offer:
(i) Product reference(s) of item(s) offered.
(ii) Brochures with photos, and technical and performance specifications.
(iii) Copy of instruction for correct use, manual in English/French/Spanish.
(iv) List of items required, but not supplied, if applicable.
(v) Copy of ISO 9001 or 13485 certificate for Quality Management System of the manufacturer. Covering design, development, production and quality assurance of the device. Kindly submit a readable copy of certificate, in English.
(vi) Confirmation of compliance with the ANSI Z87.1-2010 Standard or its update (or equivalent international standard).
(vii) Technical details and/or certificate of analysis of the coating(s)applied.

S0969026 Gloves, w/o powder, nitrile, L, disp./BOX-100

Intended Use:
To prevent contamination of the hands when providing care for patients.

General Description
HE*Gloves, without powder, nitrile, Large, disposable, box/100

Technical Specifications
- Material: nitrile
- Powder free
- Non-sterile
- Single-use disposable
- Size: large (8.5 to 9.5)
- Fits either hand
- Thickness at fingertips of ≥ 120um
- Box of 100 gloves
- CE marked - Conform to EN-455 and EN 374

Labelling on the primary packaging:
Name and/or trademark of the manufacturer.
Manufacturer's product reference.
Type of product and main characteristics. If the packaging is not transparent, it must bear a diagram (preferably actual size) showing the essential parts of the product and indicating the position of the product in the packaging.
Lot number prefixed by the word "LOT" (or equivalent harmonised symbol) (if applicable).
Expiry date by year and month, prefixed by the word "EXP" (or equivalent harmonised symbol) (if applicable).
The words "for single use" (or equivalent harmonised symbol).
The words "destroy after use" (if space allows).
Number of units per primary packaging (if applicable).
Information for particular storage conditions (temperature, pressure, light, humidity, etc.), as appropriate (or equivalent harmonised symbol).

Manufacturer's instruction for use.
Alternatively, the instruction for use can be indicated on a separate insert.

S0969025 HE*Gloves,w/opowder,nitr,M,disp,box/100

Intended Use:
To prevent contamination of the hands when providing care for patients.

General Description
HE*Gloves, without powder, nitrile, Medium, disposable, box/100

Technical Specifications
- Material: nitrile
- Powder free
- Non-sterile
- Single-use disposable
- Size: medium (7 to 8)
- Fits either hand
- Thickness at fingertips of ≥ 120um
- Box of 100 gloves
- CE marked - Conform to EN-455 and EN 374

Labelling on the primary packaging:
Name and/or trademark of the manufacturer.
Manufacturer's product reference.
Type of product and main characteristics. If the packaging is not transparent, it must bear a diagram (preferably actual size) showing the essential parts of the product and indicating the position of the product in the packaging.
Lot number prefixed by the word "LOT" (or equivalent harmonised symbol) (if applicable).
Expiry date by year and month, prefixed by the word "EXP" (or equivalent harmonised symbol) (if applicable).
The words "for single use" (or equivalent harmonised symbol).
The words "destroy after use" (if space allows).
Number of units per primary packaging (if applicable).
Information for particular storage conditions (temperature, pressure, light, humidity, etc.), as appropriate (or equivalent harmonised symbol).

Manufacturer's instruction for use.
Alternatively, the instruction for use can be indicated on a separate insert.

S0305138 Gown,surgic,nonsterile,nonwoven,disp,L

Intended Use:
To protect skin and prevent soiling or contamination of clothing during procedures and patient-care activities.

General description:
Gown, surgical, non-sterile, non-woven, disposable, L

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: L

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

Packaging and labelling:
Primary packaging is unit of use – one folded surgical gown
. Labelling on primary packaging must include:
- Name and/or trademark of the manufacturer
- Manufacturer's product reference
- 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)
- Over packaging: Packaging unit
- Labelling on the packaging unit: Labelling to be the same as primary packaging
- Extra information required: Number of units per box

S0305140 Gown,surgic,nonsterile,nonwoven,disp,XL

Intended Use:
To protect skin and prevent soiling or contamination of clothing during procedures and patient-care activities.

General Description:
Gown, surgical, nonsterile, nonwoven, disposable, XL

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): 135 –145 cm
- Circumference (measured at waist): 140 –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: 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

Packaging and labelling:
. Primary packaging is unit of use – one folded surgical gown
Labelling on primary packaging must include:
- Name and/or trademark of the manufacturer
- Manufacturer's product reference
- Type of product and main characteristics
- If the packaging is not transparent, it must bear a diagram (preferably actual size) showing the essential parts of the product and indicating the position of the product in the packaging
- 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)
Over packaging: Packaging unit
Labelling on the packaging unit: Labelling to be the same as primary packaging.
Extra information required: Number of units per box.

S0305139 Gown,isol,nonwoven,ligt,ISO16604,disp,XL

Intended Use:
To protect skin and prevent soiling or contamination of clothing during procedures and patient-care activities.

General description:
Gown, isolation, non-woven, lightweight, meets ISO16604 or equivalent standard for viral penetration resistance, disposable.

Technical Specifications:
- Isolation gown, with long sleeves and a waist tie that binds at the back or front
- Fabric, non-woven material, f.e. SMS, SMMS, polyethylene-coated polypropylene, etc.
- Outer layer viral penetration resistant material in critical areas (full front and arms) that is infective agent tested against viral penetration at a minimum pressure of 1.75kPa
- In specific, the material passes a test for resistance to penetration by blood-borne pathogens such as:
    - ISO 16604:2004, at Class 2 or higher or
    - ASTM F1671 or
    - Equivalent international standard
- Minimum average material density: 20 g/m2
- Length (measured at front from middle of neckline to bottom): 135 –145 cm
- Circumference (measured at waist): 140–146 cm
- Sleeves finished with double layer cuff, cotton or synthetic, stretchy interlocked jersey, length: 4 - 8 cm
- Non-sterile
- Single use, disposable
- Size: XL

Conform requirements of EU Medical Devices Directive 93/42, Class I (or equivalent internationally recognised marketing clearance) and/or EU Personal Protective Equipment Regulation (EU) 2016/425, Category I (or equivalent internationally recognised marketing clearance)

Packaging and labelling:
Packaging: 10 pcs. / bag
Labelling on primary packaging must include:
- Name and/or trademark of the manufacturer
- Manufacturer's product reference
- Type of product and main characteristics
- If the packaging is not transparent, it must bear a diagram (preferably actual size) showing the essential parts of the product and indicating the position of the product in the packaging
- 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)

Over packaging: Packaging unit
Labelling on the packaging unit: Labelling to be the same as primary packaging.
Extra information required: Number of units per box.

S0305136 Gown,isolation,nonwoven,disp,pack10

Intended Use:
To protect skin and prevent soiling or contamination of clothing during procedures and patient-care activities.

General description:
Gown, isolation, non-woven, disposable, pack of 10

Technical specifications:
- Isolation gown, with long sleeves, a waist tie that binds at the back or front
- Fabric, non-woven material, f.e. SMS, SMMS, polyethylene-coated polypropylene, etc.
- Outer layer liquid penetration resistant in critical areas (full front and arms)
- Minimum average material density: 30 g/m2
- Length (measured at front from middle of neckline to bottom): 135– 145cm
- Width or circumference (measured at waist): minimum of 130 cm
- Sleeves finished with double layer cuff, cotton or synthetic, stretchy interlocked jersey, length: 4 - 8 cm
- Non-sterile
- Single use, disposable
- Universal size
- Conform requirements of EU Medical Devices Directive 93/42, Class I (or equivalent internationally recognised marketing clearance) and/or EU Personal Protective Equipment Regulation (EU) 2016/425, Category I (or equivalent internationally recognised marketing clearance)

Packaging and labelling:
Packaging: 10 pcs. / bag
Labelling on primary packaging must include:
- Name and/or trademark of the manufacturer
- Manufacturer's product reference
- 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)

Over packaging: Packaging unit
Labelling on the packaging unit: Labelling to be the same as primary packaging
Extra information required: Number of units per box

S0305137 Gown,isol,nonwoven,ligt,ISO16604,disp,L

Intended Use:
To protect skin and prevent soiling or contamination of clothing during procedures and patient-care activities.

General Description:
Gown, isolation, non-woven, light, ISO16604, disposable, L

Technical specifications:
- Isolation gown, with long sleeves and a waist tie that binds at the back or front
- Fabric, non-woven material, f.e. SMS, SMMS, polyethylene-coated polypropylene, etc.
- Outer layer viral penetration resistant material in critical areas (full front and arms) that is infective agent tested against viral penetration at a minimum pressure of 1.75kPa
- In specific, the material passes a test for resistance to penetration by blood-borne pathogens such as:
    - ISO 16604:2004, at Class 2 or higher or
    - ASTM F1671 or
    - Equivalent international standard
- Minimum average material density: 20 g/m2
- 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
- Non-sterile
- Single use, disposable
- Size: L

- Conform requirements of EU Medical Devices Directive 93/42, Class I (or equivalent internationally recognised marketing clearance) and/or EU Personal Protective Equipment Regulation (EU) 2016/425, Category I (or equivalent internationally recognised marketing clearance)

Packaging and labelling:
Primary packaging 10 pieces

Labelling on primary packaging must include:
- Name and/or trademark of the manufacturer
- Manufacturer's product reference
- Type of product and main characteristics
- If the packaging is not transparent, it must bear a diagram (preferably actual size) showing the essential parts of the product and indicating the position of the product in the packaging
- 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)

Over packaging: Packaging unit
Labelling on the packaging unit: Labelling to be the same as primary packaging.
Extra information required: Number of units per box.

S0305078 Cap, surgical, bouffant, non-woven

Intended Use:
To prevent soiling or contamination of hair during procedures and patient-care activities.

Technical Specifications

- Nonwoven surgical cap
- Round, bouffant surgical cap elasticated
- Colours: preferably blue or green
- Material: nonwoven polypropylene material
- Size expected: Adult model, standard size
- Single use
- Non-sterile
- Pack size: preferably Box of 100 units

S0305131 HE Apron,protect,plastic,disp/PAC-100

Intended Use:
To prevent contamination and soiling during procedures/ cleaning expected to have high volumes of fluid that might penetrate the gown (in case gowns are not full fluid resistant)

Technical Specifications:

- Single-use straight sleeveless protective apron, for use in health care settings
- Seamless liquid proof and stain resistant
- Comfortable to wear, apron has back- and neck-band strips attached (4 in total)
- Both back- and neck-band can be adjusted/fastened
- Color: white
- Material: durable environmentally friendly plastic, polyethylene (PE) with PVC coat, minimun weight 250g/m^2
- Size: 85 x 145 cm (w x l) (+/- 15%)
- Thickness, at not less than: 50 um
- Can resist water and disinfectant (ethanol 70% and chlorine solution 0.5%)
- Supplied as pack of 100 aprons

Packaging and labelling:
Primary packaging: One (1) pack roll of 100 aprons.

Labelling on the primary packaging:
Name and/or trademark of the manufacturer.
Manufacturer's product reference.
Type of product and main characteristics. If the packaging is not transparent, it must bear a diagram (preferably actual size) showing the essential parts of the product and indicating the position of the product in the packaging.
Lot number prefixed by the word "LOT" (or equivalent harmonised symbol) (if applicable).
Expiry date by year and month, prefixed by the word "EXP" (or equivalent harmonised symbol) (if applicable).
The words "for single use" (or equivalent harmonised symbol).
The words "destroy after use" (if space allows).
Number of units per primary packaging (if applicable).
Information for particular storage conditions (temperature, pressure, light, humidity, etc.), as appropriate (or equivalent harmonised symbol)

S0305129 Bootcover antiskid elasticated

General Description:
High quality heavy duty over boot cover, puncture and abrasion resistant

Technical specifications:
- High quality heavy duty over boot cover, puncture and abrasion resistant
- Entirely liquid impermeable and repellent (adequate protection against bio-hazardous liquids)
- Material: polypropylene coated on non-woven base
- Colour: white
- Antistatic treated
- Patterned/grooved sole provides excellent slip resistance, sole thickness: 5 mm
- Resistant to disinfectant (ethanol 70% and chlorine solution 0.5%)
- Total length (sole till upper-calf level: 45 cm
- Upper-calf level, elasticated and/or provided with pair of tie-straps,length 25 cm each
- Ankle level, elasticated for user-comfort
- Accommodates all boot sizes (typical range EU 40-45, UK 7-9, US 8-11)
- Fits either foot (ambidextrous)
- Single use disposable

Labelling on the primary packaging:
Name and/or trademark of the manufacturer.
Manufacturer's product reference.
Type of product and main characteristics.
If the packaging is not transparent, it must bear a diagram (preferably actual size) showing the essential parts of the product and indicating the position of the product in the packaging.
Lot number prefixed by the word "LOT" (or equivalent harmonised symbol) (if applicable).
Expiry date by year and month, prefixed by the word "EXP" (or equivalent harmonised symbol) (if applicable).
The words "for single use" (or equivalent harmonised symbol).
The words "destroy after use" (if space allows). Number of units per primary packaging (if applicable).
Information for particular storage conditions (temperature, pressure, light, humidity, etc.), as appropriate (or equivalent harmonised symbol).

Supplier to indicate, for 1 unit/set per primary packaging:
(i) Gross volume, primary packaging (in m3)
(ii) Gross weight, primary packaging (in kg)

Supplier to submit and inform with the offer:
(i) Product reference(s) of item(s) offered
(ii) Brochures with photos, and technical and performance specifications.
(iii) Copy of instruction for correct use, manual in English/French/Spanish
(iv) List of items required, but not supplied, if applicable.
(v) ISO 9001 or 13485 certificate for Quality Management System of the manufacturer. Covering design, development, production and quality assurance of the device.

S0305116 Faceshield,fog-resistant,fullface,disp

Intended Use:
Eye Protection, to avoid contamination of mucous membranes.

General Description:
Single use 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.

Technical specifications:
- Material, shield part: clear polycarbonate, thickness approx. 0.3 mm
- Size shield, down from headband, approx.: 26 x 34 cm (h x w)
- Adjustable length headband, integrated with the shield
- Width headband, approx.: 3 cm
- Front part of the headband is foam padded (length approx. 25 cm)
- Shield is anti-fog treated/coated
- Outside is coated to prevent glare from reflection

Conforms to:
CE EN 166 standard (or equivalent international standard)

Supplied with: Supplier's instruction for use

Storage conditions:
As indicated by supplier

Packaging and labelling:
Individually packaged in a transparent plastic bag.
Labelling of the primary packaging displays, at least: product name, product reference, manufacturer name, size, type and performance testing information against the mentioned standards. Information for particular storage conditions (temperature, pressure, light, humidity, etc.), as appropriate (or equivalent harmonised symbol), if applicable. All indicated at least in English

U282700 PPE

Due to the current emergency and to increase access to the needed PPE while continuing maintaining the high quality and regulatory standards. Suppliers are encouraged to use the above material number when submitting any alternative offers for any of the above products when:

- The technical specifications of the offered product are different from the detailed above
- The performance standards of the offered product do not conform to the above-mentioned standards but conform to other not mentioned standards
- The regulatory approval and market release certificates of the product is different from the above mentioned

All offers will be evaluated case by case basis and the technical decision will be taken based on:

- The confirmation of the quality and performance standards
- The updated accepted regulatory approval at the time of evaluation by WHO and CDC
- The successful sample evaluation
- The need for additional supply in case not above supplies cannot be secured