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1. Considerations

The present publication aims to define the basic Technical characteristics of Personal protective equipment. The decision as to the appropriate clinical use of each of these devices is reserved to the IPC guidance and medical staff.

2. Methodology

Technical specifications define the minimum requirements for the product to ensure good quality, safety and efficacy. The process to develop these specifications included:

1. Analysis of the required to perform the clinical management of COVID-19 patients.[1]
2. Considerations of Rational use of personal protective equipment [2]
3. Analysis of personal protective equipment and infection prevention control measures during COVID-19 including use of masks[3]
4. COVID-19 advice for the public: when and how to use masks[4]
5. Analysis of existing products in the market, based on approvals from the regulatory agencies.
6. Analysis of international, regional and country standards
7. Drafting of technical specifications and standards checklist by WHO consultants: Ying Ling Lin and Erol Ozbakir.
8. Input from the following members of the Technical Advisory Group of experts on personal protective equipment (TAG PPE), specifically group 1 on standards, technical specifications and quality assurance: Ying Ling, Erol Ozbakir, Faisal Al Shehri, Razan Asally, Patricia Ching, Nagwa Hasanin, Emilio Hornsey, Selcen Kilinc-Balci, Melissa Leavitt, Claudio Meirovich, John McGhie, and Alison Syrett, Ayse Ayzit Kilinc, Nasri Yussuf. All members of TAG PPE have provided Conflict of Interest documents, which have been reviewed by WHO and no conflicting interests have been found.
9. Revision, technical input and alignment to WHO guidelines and guidance, from WHO staff (including PAHO, EURO, SEARO, EMRO): April Baller, Murilo Freitas, Bruce Gordon, Tifenn Humbert, Agnes Kijo, Alexandre Lemgruber, Fernanda Lessa, Ismail Mohamed, Houda Langar, Madison Moon, Antoine Delaitre and Adriana Velazquez
10. Coordination by Adriana Velazquez, Group Lead for medical devices and in vitro diagnostics, WHO.

[1] 1. https://www.who.int/emergencies/diseases/novel-coronavirus-2019/technical-guidance/patient-management

[2] https://www.who.int/publications/i/item/rational-use-of-personal-protective-equipment-for-coronavirus-disease-(covid-19)-and-considerations-during-severe-shortages

[3] https://www.who.int/publications/i/item/advice-on-the-use-of-masks-in-the-community-during-home-care-and-in-healthcare-settings-in-the-context-of-the-novel-coronavirus-(2019-ncov)-outbreak

[4] https://www.who.int/emergencies/diseases/novel-coronavirus-2019/advice-for-public/when-and-how-to-use-masks

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3. Regulatory approvals and certifications

For all the personal protective equipment and related Infection prevention control supplies the following regulatory approvals, and certifications apply.

It should be noted that in some economic regions, some personal protective equipment is considered a medical device and therefore follow respective regulations.

In other regions, some protective equipment, might be considered only an industrial protection garment and not tagged for medical use.

Due to the limited manufacturing some products might be coming from other economic regions or might have "emergency use authorizations" by regulatory agencies. Therefore, the requirements listed below might apply only to the COVID-19 period and may be updated, otherwise will be valid for up to two years after publication.

Naming	Names, synonym
General technical requirements	See Section 2 for technical specifications of PPE specific for Covid-19
Primary packaging	Labelling on the primary packaging need to include: Name and/or trademark of the manufacturer. Model or product's reference. Information for particular storage conditions (temperature, pressure, light, humidity).
Quality Management System from the manufacturer, for the PPE types	Certified quality management system for medical devices (e.g. ISO 13485) and application of risk management to medical devices (e.g. ISO 14971). General quality management (e.g. ISO 9001), (for case of non-medical devices). EU Module C2 or D Conformity to type Certificate (Cat. III CE Certified PPE only).
Regulatory approval/certification	Free sales certificate (FSC) of medical device and related IPC products. Certificate for exportation of medical device and related IPC products, provided by the authority in manufacturing country (in case of imported goods). National local regulatory approval (of recipient country, as applicable).

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	Proof of regulatory compliance, as appropriate, per the product's risk classification (e.g. Europe: CE Certification and declaration of conformity &/or EU type examination certificate as applicable e.g. PPE cat. III for respirators; e.g. US: Food and Drug Administration approval [FDA] or Emergency use authorization; China NMPA listed). Ability for purchaser to check authenticity directly with the issuing regulatory authority (e.g., online database of active licenses). Category I PPE, may accept self-declaration with declaration of conformity. Covid-19 context. Authorized representative must be identified and document expiration date (valid until).
Test reports	Official test reports (all pages, in English), must either originate from accredited test labs, whereby the accreditation authority is preferably members of ILAC (International Laboratory Accreditation Cooperation), or from an EU notified body. Accredited facilities should be ISO 17025 certified. Test reports should clearly indicate the accredited laboratory name and accreditation, (for regulator or procurer, to be able to check authenticity of test reports) Test standard must be within the scope of the accreditation of the laboratory. CE certificates (EU type examination certificates) for category III PPE should mention the Notified Body name/number. Instructions for authentication of the test report(s) & certificates should be provided. Ability for purchaser to check authenticity directly with the accredited test laboratory (e.g., online uploading of test report and automatic version check, or emailing test facility).

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4. Minimum requirements for procurement of Personal protective equipment (technical specifications)

Item	CHARACTERISTICS	Performance standards
Gloves, examination, non-sterile	Gloves, examination, nitrile (preferable), latex, polychloroprene or PVC, powder-free, non-sterile. (e. g., minimum 230mm total length). Minimum thickness 0.05mm. Sizes S, M, L.	• EN 455, • EN 374, optional additional: • ASTM D6319, D3578, D5250, D6977 or alternative equivalent set of standards
Gloves, surgical, sterile	Gloves, surgical, nitrile (preferable), latex, polyisoprene, or polychloroprene, sterile, powder-free, single use. Gloves should have long cuffs, reaching well above the wrist, ideally to mid-forearm. minimum thickness 0.10mm. Sizes ranging 5.0 - 9.0.	• EN 455, • ASTM D3577, Sterility • United States Pharmacopeia • EN ISO 11607 or alternative equivalent set of standards
Goggles, glasses protective	Good seal with the skin of the face, Flexible PVC frame to easily fit with all face contours with even pressure, Enclose eyes and the surrounding areas, Accommodate wearers with prescription glasses, Clear plastic lens with fog and scratch resistant treatments, Adjustable band to secure firmly so as not to become loose during clinical activity, Indirect venting to avoid fogging, May be re-usable (provided appropriate arrangements for decontamination are in place) or disposable.	• EN 166, • ANSI/ISEA Z87.1, or alternative equivalent set of standards
Face shield	Made of clear plastic and providing good visibility to both the wearer and the patient. Adjustable band to attach firmly around the head and fit snuggly against the forehead, fog	• EN 166 (if reusable), • ANSI/ISEA Z87.1 (if reusable), or alternative equivalent set of standards

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Item	CHARACTERISTICS	Performance standards
	resistant (preferable). Completely cover the sides and length of the face. May be re-usable (made of robust material which can be cleaned and disinfected) or disposable.	
Fit test kit	To evaluate effectiveness of seal for tight fitting respiratory protection devices	OSHA 29 CFR 1910.134 Appendix A
Particulate respirator	Good particle filtration (minimum 94% or 95%), good breathability with design that does not collapse against the mouth (e.g. duckbill, cup-shaped). May be tested for fluid resistance (NIOSH/FDA surgical N95, EN 149 FFP2+Type IIR, GB 19083 Grade/Level 1)	Fluid resistant respirator: • Minimum NIOSH approved (42 CFR Part 84) and FDA cleared "surgical N95" • EN 149, minimum "FFP2" and EN 14683 Type IIR • GB 19083, minimum "Grade/Level 1", or alternative equivalent standard Non-fluid resistant respirator • Minimum NIOSH approved"N95" according to 42 CFR Part 84 • EN 149, minimum "FFP2" • GB 2626, minimum "KN95" or alternative equivalent standard

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Item	CHARACTERISTICS	Performance standards
Mask, medical - for healthcare worker	Medical mask, good breathability, internal and external faces should be clearly identified, 98% droplet filtration, preferably fluid resistance.	Fluid resistant masks (surgical masks): • EN 14683 Type IIR • ASTM F2100 Level 1, 2 or 3, • YY 0469, with at least 98% bacterial droplet filtration or alternative equivalent standard Non-fluid resistant mask: • EN 14683 Type II • YY/T 0969, with at least 98% bacterial droplet filtration or alternative equivalent standard
Mask, medical, for patient	Medical mask, good breathability, internal and external faces should be clearly identified	• EN 14683 Type I • YY 0469 or YY/T 0969, if bacterial droplet filtration is below 98% or alternative equivalent standard
Scrubs, tops	Tunic/tops, woven, scrubs, reusable or single use, short sleeved (tunic/tops), worn underneath the coveralls or gown.	
Scrubs, pants	Trouser/pants, woven, scrubs, reusable or single use, worn underneath the coveralls or gown	

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Item	CHARACTERISTICS	Performance standards
Apron, heavy duty	Straight apron with bib, Fabric: 100% polyester with PVC coating, or 100% PVC, or 100% rubber, or 100% reusable and biodegradable material, or other fluid resistant coated material, Waterproof, sewn strap for neck and back fastening or single-material cut film Minimum basis weight: 300 g/m2, Thickness: 200-300 microns, optional Covering size: 70 - 90 cm (width) x 120 - 150 cm (height), Reusable (provided appropriate arrangements for decontamination are in place) or biodegradable	• EN ISO 13688 • EN 14126 and partial protection (EN 13034 or EN 14605) • EN 343 for water and breathability or alternative equivalent set of standards If biodegradable, • EN 13432, • ASTM D6400
Apron, disposable	Single-use straight sleeveless protective apron, for use in healthcare 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: polyethylene (PE) or biodegradable or compostable material 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 0.05% or 500ppm)	Product Performance testing if biodegradable • EN 13432, • ASTM D6400 or alternative equivalent set of standards
Gown, isolation	Single use, disposable, made of nonwoven material, length mid-calf. Sizes S, M, L, XL	• AAMI PB70 (Level 1-3) and ASTM F3352,

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Item	CHARACTERISTICS	Performance standards
	May also be reusable, woven, length mid-calf, sizes S, M, L, XL. Critical zones may be more fluid resistant than non-critical zones. Reusable gowns should meet the minimum performance requirements after maximum suggested laundering cycles.	• EN 13034 - Type PB [6] (stitched gown), with minimum hydrostatic head of 50 cm H2O • AAMI PB70 Level 4 and ASTM F3352 or • ISO 16604 Class 5 or alternative equivalent set of standards
Gown, surgical	Single use, disposable, nonwoven material, length mid-calf, sterile or non-sterile. Critical zones may be more fluid resistant than non-critical zones. Or Single use, woven material, length mid-calf, sterilizable. Critical zones may be more fluid resistant than non-critical zones. Reusable gowns should meet the minimum performance requirements after maximum suggested laundering cycles.	• AAMI PB70 and ASTM F2407 • EN 13795 • EN 13034 - Type PB [6] (stitched gown), with minimum hydrostatic head of 50 cm H2O • YY/T 0506 or alternative equivalent set of standards • EN 556, if sterile or alternative equivalent set of standards
Alcohol-based hand rub	Bottle of 100ml & 500ml, at least 80% ethanol or 75% isopropyl alcohol (v/v)	• ASTM E2755, or • EN 1500 or alternative equivalent set of standards Optional: • ASTM E1115, or • ASTM E1174

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Item	CHARACTERISTICS	Performance standards
Bio-hazard bag	Disposable autoclavable bag for biohazard waste Material: High Density Polyethylene (HDPE) or Polypropylene (PP) Colour: red or yellow Autoclave ability (temperature resistant up to 121℃) Printed with a sterilization patch that darkens when subject to steam Puncture, tear and leak resistant Leak proof flat bottom seal Black imprint "Biohazard" and tri-sickle logo according U+2623 on one side Capacity: Approximately 20L or 50L Thickness: min 0.038mm (1.5mil) Sizes: - width (45 cm), length (50 cm) (±10%) - width (60 cm), length (82 cm) (±10%)	• Puncture resistant meets ASTM D1709 (dart impact test) • Tear resistant meets ASTM D1922 or ISO 6383-2 • Temperature Resistance test at 121℃;
Safety box	SAFETY BOX, needles/syringes, 5 L capacity, cardboard for incineration, box-25	Biohazard label as per WHO PQS E010/011
Soap	Liquid (preferred), powder and bar	

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Item	CHARACTERISTICS	Performance standards
Gloves, cleaning	Glove should have long cuffs, reaching well above the wrist, ideally to mid-forearm, Minimum 280 mm total length Sizes: S, M, L Reusable heavy duty gloves, High cracking-, puncture- and abrasion resistant Powder free, Seamless, and entirely waterproof Made of Nitrile, synthetic rubber (no Latex), Knit inner lining facilitates slide-in and removal Cleanable with water and disinfectant (resisting both ethanol solutions 70% and chlorine solutions 0.05% or 500ppm) Material thickness, at level of the fingers, not less than: 0.38mm Length not less than: 30cm Supply co-packed as one left/right pair	EN 388 ANSI 105 EN 374-1, EN 374-2 (at least level 2), EN 374-4 and EN 374-5 EN 420 + A1 or alternative equivalent set of standards
Hand drying tissue	50 to 100 m roll	
Chlorine	NaDCC, granules, 1kg, 65 to 70% + measurement spoon	

5. References and resources

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4. PAHO, Technical and Regulatory Aspects of the Extended Use, Reuse, and Reprocessing of Respirators during Shortages, 10 June 2020 https://iris.paho.org/handle/10665.2/52431
5. Commission recommendation (EU) 2020/403 of 13 March 2020 https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32020H0403
6. AAMI: https://www.aami.org/detail-pages/press-release/aami-offers-free-standards-and-resources-to-help-fight-coronavirus
7. EN: https://www.bsigroup.com/en-GB/topics/novel-coronavirus-covid-19/medical-devices-ppe/
8. ISO: https://www.iso.org/covid19
9. ASTM: https://www.astm.org/COVID-19
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Annex 1. Tables of standards and values (not exhaustive)

A1.1 Respirators

A1.2 medical masks

A1.3 isolation and surgical gowns

A1.4 examination and surgical gloves

Respirators

	Europe (EN 149)	USA (NIOSH CFR PART 84)	China (GB 2626)	China (GB 19083)
Filtration (NaCl)	≥ 94% (FFP2)	≥ 95% (N95)	≥ 95% (KN95)	≥ 95% (Grade 1)
Breathing resistance (inhalation)	≤ 70 Pa (@ 30 L/min) ≤ 240 Pa (@ 95 L/min) ≤ 500 Pa (clogging)	≤ 343 Pa () (@ 85L/min)	≤ 350 Pa (@ 85L/min)	≤ 343 Pa (@ 85L/min)
Breathing resistance (exhalation)	≤ 300 Pa (@160 L/min)	≤ 245 Pa (@ 85L/min)	≤ 250 Pa (@85 L/min)	
Fit	Tested with 10 human participants	Fit testing upon arrival	10 participants	Fit factor of 100, with 8 subjects
Total inward leakage	≤ 8% leakage (arithmetic mean)	n/a	≤ 8% leakage (arithmetic mean)	

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CO2 of inhalation air	≤ 1%	n/a	≤ 1%	
Synthetic Blood penetration	If Type IIR 120 mm Hg (≥29/32 passing masks	If surgical N95, 120 mm Hg (≥29/32 passing masks)	none	If surgical N95, 120 mm Hg (5 masks)
Other criteria	Requires passing paraffin oil filtration at 95%			

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Masks, medical

	Europe (EN 14683)	US (ASTM F2100)	China (YY 0469)	China (YY 0969)
Filtration (BFE)	≥95% (Type I) ≥98% (Type II, IIR)	≥95% (Level 1) ≥98% (Level 2, 3)	≥95% (ASTM F2101)	≥95% (ASTM F2101)
Filtration (PFE)	N/A	≥95% (Level 1) ≥98% (Level 2, 3)	N/A	N/A
Pressure drop (Pa/cm2)	<40 (Type I, II) <60 (Type IIR)	mm H2O/cm2 <49 Pa or 5 mm H2O/cm2 (Level I) <58.8 Pa or 6 mm H2O (Level II, III)	<49	<49
Synthetic Blood penetration (kPa)	120 mm Hg ISO 22609 ≥16 kPa (Type IIR)	80 mm Hg (Level I) 120 mm Hg or 16 kPa (Level II) 160 mm Hg (Level III)	120 mm Hg =16kPa	N/A
Microbial cleanliness (cfu/g)	≤30	N/A	≤100	≤100

Gowns, isolation/surgical

	Europe (EN 13795)	US (AAMI PB70, ASTM F3352, ASTM F2407)	China (YY T/0506)
Water resistance (impact penetration)		<4.5 g (AAMI Level 1) ≤ 1.0 g (AAMI Level 2 and 3) (AQL 4%, RQL=20%	

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Water resistance (hydrostatic pressure)	≥ 20 cm H2O (critical area, std performance) ≥ 100 cm H2O (critical area, high performance) ≥ 10 cm H2O (less critical area, std and high performance)	≥ 20 cm (AAMI Level 2) ≥ 50 cm (AAMI Level 3) (AQL 4%, RQL=20%	≥ 20 cm H2O (critical area, std performance) ≥ 100 cm H2O (critical area, high performance) ≥ 10 cm H2O (less critical area, std and high performance)
Viral penetration		Pass (AQL 4%, RQL=20% (AAMI Level 4)	
Resistance to wet bacterial penetration	≤ 2.8 I_B (critical areas, std performance) ≤ 6.0 I_B (critical areas, high performance)		≤ 2.8 I_B (critical areas, std performance) ≤ 6.0 I_B (critical areas, high performance)
Resistance to dry microbial penetration	≤ 300 CFU (less critical areas, std and high performance)		≤ 300 CFU (less critical areas, std and high performance)
Cleanliness microbial	≤ 300 CFU (all areas, std and high performance)		≤ 300 CFU (all areas, std and high performance)
Bursting strength (Dry)	≥ 40 kPa (all areas, std and high performance)		≥ 40 kPa (all areas, std and high performance)
Bursting strength (Wet)	≥ 40 kPa (critical areas, std and high performance)		≥ 40 kPa (critical areas, std and high performance)
Tensile strength (Dry)	≥ 20 N (all areas, std and high performance)	≥ 30 N	≥ 20 N (all areas, std and high performance)
Tensile strength (Wet)	≥ 20 N (crit. areas, std and high performance)		≥ 20 N (crit. areas, std and high performance)
Other criteria to consider		Optional: - Water vapor transmission	China (GB 38462) gown standard, in effect October 2020

		Rate (ASTM D6701) - Evaporative resistance (ASTM F1868, Part B)	

Gloves, medical examination (non-sterile)

	Europe (EN 455)	**US (ASTM material specific)**
	EN 455-1, EN 455-2, EN 455-3, EN 455-4	**D6319, D3578, D5250, D6977**
Freedom from holes	AQL < 1.5 (ISO 2859)	AQL < 2.5 (ISO 2859)
Force at break (N) / Tensile strength (MPa) (after aging)	AQL – N/A Nitrile >6.0N Latex (natural) >6.0N Polyisoprene >6.0N Polychloroprene> 6.0N PVC, PE > 3.6N	AQL < 4.0 (ISO 2859) Nitrile >14MPa Latex (natural) >14MPa Polychloroprene >14MPa PVC >11MPa
Powder residue content	<2.0mg	<2.0mg
Aqueous soluble protein content	<10 µg per g of glove	<200 µg/dm2
Extractable antigenic protein content		<10 µg/dm2

Gloves, surgical (sterile)

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	Europe (EN 455)	**US (ASTM material specific)**
	EN 455-1, EN 455-2, EN 455-3, EN 455-4	**D3577**
Freedom from holes	AQL < 1.5 (ISO 2859)	AQL < 1.5 (ISO 2859)
Force at break (N) / Tensile strength (MPa) (after aging)	AQL – N/A All materials > 9.0N	AQL < 4.0 (ISO 2859) Type 1- Latex (natural) >18MPa Type 2- Polyisoprene, Polychloroprene, Nitrile >12MPa
Powder residue content	<2.0mg	<2.0mg
Aqueous soluble protein content	<10 µg per g of glove	<200 µg/dm2
Extractable antigenic protein content		<10 µg/dm2
Sterility	ASTM refers o U.S. Pharmacopeia: pass/fail EN 455 refers to EN ISO 11607	

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Annex 2. Checklists

Developed by WHO consultant Ying Ling Lin to review compliance of standards for:

2.1 respirator

2.2 medical mask

2.3 examination gloves

2.4 surgical sterile gloves

2.5 isolation and surgical gowns

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Technical compliance to relevant performance standards – face filtering respirator
Supplier:

Manufacturer:

Model:

Standard Test Title	Reference Standard	Minimum acceptable performance level	Compliant		Claimed performance (Class, Type, or measured)	Year/Version of standard	Reference document (.pdf)
			YES	No			
Test report origin							
ILAC accredited lab	ISO 17025	Compliant	☐	☐			
National NB	ISO 17025	Compliant	☐	☐			
Local, non-accredited	ISO 17025	Compliant	☐	☐			
Whole respirator performance							
Europe Respirators	EN 149	FFP2	☐	☐			
	EN 149	FFP3	☐	☐			
US Respirators	NIOSH	N95	☐	☐			
	NIOSH	N99	☐	☐			
	NIOSH	N100	☐	☐			

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Standard Test Title	Reference Standard	Minimum acceptable performance level	Compliant		Claimed performance (Class, Type, or measured)	Year/Version of standard	Reference document (.pdf)
			YES	No			
	NIOSH	Surgical N95	☐	☐			
Korea Respirators	KMOEL - 2017-64	1st Class	☐	☐			
China Respirators	GB2626	KN95	☐	☐			
	GB 19083	Grade 1	☐	☐			
Australia Respirators	AS/NZA 1716	P2	☐	☐			
Japan Respirators	JMHLW-Notification 214	DS	☐	☐			
Physical performance/characteristics							
Filter penetration of NaCl dry aerosol (at 95 L/min air flow)	EN 149, Clause 7.9.2	<6% (FFP2)	☐	☐			
		<1% (FFP3)	☐	☐			
Filter penetration of paraffin aerosol (at 95 L/min air flow)	EN 149, Clause 7.9.2	<6% (FFP2)	☐	☐			
		<1% (FFP3)	☐	☐			

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Standard Test Title	Reference Standard	Minimum acceptable performance level	Compliant		Claimed performance (Class, Type, or measured)	Year/Version of standard	Reference document (.pdf)
			YES	No			
Filter penetration of NaCl dry aerosol (at 30 L/min air flow)	Filters >94% of NaCl particles of 2.5 μm	<6%	☐	☐			
Filter penetration of NaCl dry aerosol (at 85 L/min air flow)	NIOSH 42 CFR 84 (N95)	>95% particle removal efficiency	☐	☐			
	GB 19083 (Grade 1)	>95% particle removal efficiency	☐	☐			
Total inward leakage (TIL)	EN 149 Clause 7.9.1	<11%, FFP2 < 8%, mean	☐	☐			
	EN 149 Clause 7.9.1	<5%, FFP3 2% (mean)	☐	☐			
CO2 in inhalation air	EN 149 Clause 7.12	<1%	☐	☐			
Synthetic blood penetration (Surgical N95)	ASTM F1862	80 mmHg	☐	☐			
		120 mmHg	☐	☐			
		160 mmHg	☐	☐			
Synthetic blood penetration	ISO 22609	120 mmHg	☐	☐			

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Standard Test Title	Reference Standard	Minimum acceptable performance level	Compliant		Claimed performance (Class, Type, or measured)	Year/Version of standard	Reference document (.pdf)
			YES	No			
(FFP2 with fluid resistance)							
Synthetic blood penetration	GB 19083	80 mm Hg	☐	☐			
Synthetic blood penetration	GB 19083 (Grade 1), reference (YY/T 0691-2008)	Need test reference	☐	☐			
Flammability	16 CFR Part 1610	Class 1	☐	☐			
	EN 149, Clause 7.11	< 5 seconds	☐	☐			
	GB 19083, 4.10	< 5 seconds	☐	☐			
Compatibility with skin	EN 149, Clause 7.10	-	☐	☐			
	GB 19083, 4.11	Max score of 1	☐	☐			
shelf life*		5 years	☐	☐			
Comfort characteristics							
Breathing resistance (inhalation) @ 30 L/min	EN 149, Clause 7.16	Max 0.7 mbar (FFP2)	☐	☐			

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Standard Test Title	Reference Standard	Minimum acceptable performance level	Compliant		Claimed performance (Class, Type, or measured)	Year/Version of standard	Reference document (.pdf)
			YES	No			
		70 Pa					
		Max 1.0 mbar (FFP3) 100 Pa	☐	☐			
Breathing resistance (inhalation) @ 95 L/min	EN 149, Clause 7.16	Max 2.4 mbar (FFP2) 240 Pa	☐	☐			
		Max 3.0 mbar (FFP3) 300 Pa	☐	☐			
Breathing resistance (exhalation) @ 160 L/min	EN 149, Clause 7.16	Max 3.0 mbar (FFP2 and FFP3) 300 Pa	☐	☐			
Breathing resistance (inhalation/exhalation) @ 95 L/min	EN 149, Clause 7.17.2.2	Max 4 mbar, after clogging (FFP2)	☐	☐			

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Standard Test Title	Reference Standard	Minimum acceptable performance level	Compliant		Claimed performance (Class, Type, or measured)	Year/Version of standard	Reference document (.pdf)
			YES	No			
Breathing resistance (inhalation) @85 L/min	Surgical N95	Max 3.5 mbar 350 Pa	☐	☐			
	GB 19083	343.2 Pa	☐	☐			
Breathing resistance (exhalation) @85 L/min	Surgical N95	Max 2.5 mbar 250 Pa	☐	☐			
Breathing resistance @30 (inhalation) L/min	Korea 1st Class (KMOEL - 2017-64)	≤ 70 Pa (at 30 L/min) ≤ 240 Pa (at 95 L/min)	☐	☐			
Breathing resistance (exhalation) @160 L/min	Korea 1st Class (KMOEL - 2017-64)	≤ 300 Pa	☐	☐			
Breathing resistance (inhalation) @85 L/min	GB2626, KN95	Max 350 Pa	☐	☐			
Breathing resistance (exhalation) @85 L/min	GB2626, KN95	Max 210 Pa	☐	☐			

COVID-19 Technical Specifications for Personal Protective Equipment and Related IPC supplies

Standard Test Title	Reference Standard	Minimum acceptable performance level	Compliant		Claimed performance (Class, Type, or measured)	Year/Version of standard	Reference document (.pdf)
			YES	No			
Quality compliance							
General quality management system	ISO 9001	Compliance	☐	☐			
Medical device quality management	ISO 13485	Compliance	☐	☐			
Sampling procedures for inspection by attribute	ISO 2859	Compliance	☐	☐			
Regulatory compliance							
Establishment licence	US FDA database	Active	☐	☐			
Listed as an acceptable respirator	NIOSH	Active listing	☐	☐			
Listed as a non-NIOSH acceptable respirator	US FDA Emergency Use Authorization	Active listing	☐	☐			
Medical device license	US FDA database	Active	☐	☐			

COVID-19 Technical Specifications for Personal Protective Equipment and Related IPC supplies

Standard Test Title	Reference Standard	Minimum acceptable performance level	Compliant		Claimed performance (Class, Type, or measured)	Year/Version of standard	Reference document (.pdf)
			YES	No			
Medical Devices Active Licence Listing	Health Canada (MDALL)	Active	☐	☐			
CE/EC certification	PPE Regulation 2016/425	Compliance	☐	☐			
MHRA	UK	Compliance	☐	☐			
KOSHA	Korea KMOEL - 2017-64	Compliance	☐	☐			
Manufacturers allowed to export	National Medical Products Administration	Active licence/permit	☐	☐			
Manufacturers cleared for local sale	National Medical Products Administration	Active licence/permit	☐	☐			

COVID-19 Technical Specifications for Personal Protective Equipment and Related IPC supplies

Technical compliance to relevant performance standards for medical face masks

Supplier:

Manufacturer:

Model:

Standard Test Title	Reference Standard	Minimum acceptable performance level	Compliant		Claimed performance (Class, Type, or measured)	Year/Version of standard	Reference document (.pdf)
			YES	No			
Test report origin							
ILAC accredited lab	ISO 17025	Compliant	☐	☐			
National Notifying Body	ISO 17025	Compliant	☐	☐			
Local, non-accredited	ISO 17025	Compliant	☐	☐			
Whole mask performance							
Materials used in medical face masks	ASTM F2100	Level 1	☐	☐			
	ASTM F2100	Level 2	☐	☐			
	ASTM F2100	Level 3	☐	☐			

COVID-19 Technical Specifications for Personal Protective Equipment and Related IPC supplies

Standard Test Title	Reference Standard	Minimum acceptable performance level	Compliant		Claimed performance (Class, Type, or measured)	Year/Version of standard	Reference document (.pdf)
			YES	No			
Requirements and test methods for medical face masks	EN 14683	Type I	☐	☐			
	EN 14683	Type II	☐	☐			
	EN 14683	Type IIR	☐	☐			
Surgical mask (fluid resistant)	YY 0469	Compliant	☐	☐			
Single-use medical face mask	YY/T 0969	Compliant	☐	☐			
Physical performance/characteristics							
Droplet Filtration efficiency (3.0 µm particle size)	ASTM F2101	95% AQL 4%, RQL=20%	☐	☐			
	ASTM F2101	98% AQL 4%, RQL=20%	☐	☐			
	YY 0469	95% AQL 4%, RQL=20%	☐	☐			

COVID-19 Technical Specifications for Personal Protective Equipment and Related IPC supplies

Standard Test Title	Reference Standard	Minimum acceptable performance level	Compliant		Claimed performance (Class, Type, or measured)	Year/Version of standard	Reference document (.pdf)
			YES	No			
Droplet Filtration efficiency (3.0 µm particle size)	YY 0469	80 mmHg AQL 4%, RQL=20%	☐	☐			
Droplet Filtration efficiency (3.0 µm particle size)	YY/T 0969	120 mmHg AQL 4%, RQL=20%	☐	☐			
	YY 0469	160 mmHg AQL 4%, RQL=20%	☐	☐			
Filtration efficiency (0.1 µm particle size)	ASTM F2299	Class 1 AQL 4%, RQL=20%	☐	☐			
Synthetic blood penetration	ASTM F1862	95% AQL 4%, RQL=20%	☐	☐			
		98% AQL 4%, RQL=20%	☐	☐			
		95% AQL 4%, RQL=20%	☐	☐			

COVID-19 Technical Specifications for Personal Protective Equipment and Related IPC supplies

Standard Test Title	Reference Standard	Minimum acceptable performance level	Compliant		Claimed performance (Class, Type, or measured)	Year/Version of standard	Reference document (.pdf)
			YES	No			
Flammability	16 CFR Part 1610	80 mmHg AQL 4%, RQL=20%	☐	☐			
Biocompatibility		-	☐	☐			
Number of layers	-	Minimum 3	☐	☐			
Basis weight	ASTM D3776	-	☐	☐			
shelf life		5 years	☐	☐			
Comfort characteristics							
Differential pressure	MIL-M-36945C 4.4.1.1.1 Method 1 or EN14683	<3.0 mm H_2O/cm^2, 29.4 Pa/cm^2	☐	☐			
		<4.0 mm H_2O/cm^2, 39.2 Pa/cm^2	☐	☐			
		<5.0 mm H_2O/cm^2,	☐	☐			

COVID-19 Technical Specifications for Personal Protective Equipment and Related IPC supplies

Standard Test Title	Reference Standard	Minimum acceptable performance level	Compliant		Claimed performance (Class, Type, or measured)	Year/Version of standard	Reference document (.pdf)
			YES	No			
		49.0 Pa/cm^2					
Quality compliance							
General quality management system	ISO 9001	Compliant	☐	☐			
Medical device quality management	ISO 13485	Compliant	☐	☐			
Sampling procedures for inspection by attribute, post shipment	ISO 2859	Compliant	☐	☐			
Regulatory clearance							
EU PPE Regulation 2016/425		Valid, issued <5 years	☐	☐			
EN MD Directive 93/42/EEC		Valid, issued <5 years	☐	☐			

COVID-19 Technical Specifications for Personal Protective Equipment and Related IPC supplies

Standard Test Title	Reference Standard	Minimum acceptable performance level	Compliant		Claimed performance (Class, Type, or measured)	Year/Version of standard	Reference document (.pdf)
			YES	No			
US FDA 510(k)		Valid, issued <5 years	☐	☐			
NMPA, export clearance		Valid, issued <5 years	☐	☐			
NMPA, internal use		Valid, issued <5 years	☐	☐			

COVID-19 Technical Specifications for Personal Protective Equipment and Related IPC supplies

Technical compliance to relevant performance standards for examination gloves (non-sterile)
Supplier:

Manufacturer:

Model:

Standard Test Title	Reference Standard	Minimum acceptable performance level	Compliant		Claimed performance (Class, Type, or measured)	Year/Version of standard	Reference document (.pdf)
			YES	No			
Test report origin							
ILAC accredited lab	ISO 17025	Compliant	☐	☐			
National Notifying Body	ISO 17025	Compliant	☐	☐			
Local, non-accredited	ISO 17025	Compliant	☐	☐			
Whole glove performance							
Standard Specification for Nitrile Examination Gloves for Medical Application	ASTM D6319	Compliant	☐	☐			
Terminology and performance	EN ISO 374-1	Type A	☐	☐			
		Type B	☐	☐			

COVID-19 Technical Specifications for Personal Protective Equipment and Related IPC supplies

Standard Test Title	Reference Standard	Minimum acceptable performance level	Compliant		Claimed performance (Class, Type, or measured)	Year/Version of standard	Reference document (.pdf)
			YES	No			
requirements for chemical risks		Type C	☐	☐			
Determination of resistance to penetration	EN ISO 374-2	Compliant	☐	☐			
Determination of resistance to degradation by chemicals	EN ISO 374-4	Compliant	☐	☐			
Terminology and performance requirements for micro-organisms risks	EN ISO 374-5	Compliant	☐	☐			
Medical gloves for single use - Part 1: Requirements and testing for freedom from holes	EN 455-1	Compliant	☐	☐			
Medical gloves for single use - Part 2:	EN 455-2	Compliant	☐	☐			

COVID-19 Technical Specifications for Personal Protective Equipment and Related IPC supplies

Standard Test Title	Reference Standard	Minimum acceptable performance level	Compliant		Claimed performance (Class, Type, or measured)	Year/Version of standard	Reference document (.pdf)
			YES	No			
Requirements and testing for physical properties							
Medical gloves for single use - Part 3: Requirements and testing for biological evaluation	EN 455-3	Compliant	☐	☐			
Medical gloves for single use - Part 4: Requirements and testing for shelf life determination	EN 455-4	Compliant	☐	☐			
Penetration/ Freedom from holes							
Water test	ASTM D6319 (ASTM D5151)	AQL < 2.5, G1	☐	☐			
Water tightness test	EN 455-1	AQL < 1.5	☐	☐			

COVID-19 Technical Specifications for Personal Protective Equipment and Related IPC supplies

Standard Test Title	Reference Standard	Minimum acceptable performance level	Compliant		Claimed performance (Class, Type, or measured)	Year/Version of standard	Reference document (.pdf)
			YES	No			
Water leak/Air leak test	EN ISO 374-2 (ISO 2895)	Level 3 AQL <0.65, G1	☐	☐			
		Level 2 AQL <1.50, G1	☐	☐			
		Level 1 AQL <4.50, S4	☐	☐			
Material strength characteristics							
Tensile strength (before aging)	ASTM D6319	>14MPa AQL<4.0, S2	☐	☐			
Tensile strength (after aging)		>14MPa AQL<4.0, S2	☐	☐			
Elongation (before aging)		>500% AQL<4.0, S2	☐	☐			
Elongation (after aging)		>400% AQL<4.0, S2	☐	☐			

COVID-19 Technical Specifications for Personal Protective Equipment and Related IPC supplies

Standard Test Title	Reference Standard	Minimum acceptable performance level	Compliant		Claimed performance (Class, Type, or measured)	Year/Version of standard	Reference document (.pdf)
			YES	No			
Breaking force (before aging)	EN 455-2	>6.0N	☐	☐			
Breaking force (after aging)		>6.0N	☐	☐			
Powder residue							
Powder free	ASTM D6319	<2.0mg (N=5)	☐	☐			
Powder free	EN 455-3	<2.0mg	☐	☐			
Powdered	ASTM D6319	max 10 mg/dm2 (N=2)	☐	☐			
Powdered	EN 455-3	>2.0mg	☐	☐			
Size							
Thickness	ASTM D6319	Finger >0.05mm AQL<4.0, S2	☐	☐			

COVID-19 Technical Specifications for Personal Protective Equipment and Related IPC supplies

Standard Test Title	Reference Standard	Minimum acceptable performance level	Compliant		Claimed performance (Class, Type, or measured)	Year/Version of standard	Reference document (.pdf)
			YES	No			
		Palm >0.05mm AQL<4.0, S2	☐	☐			
	EN 455	N/A					
Length	EN 455-2 (all sizes)	l≥ 240mm	☐	☐			
	ASTM D6319 (xs,s and 6-7)	l≥ 220mm AQL<4.0,S2	☐	☐			
	ASTM D6319 (uni,m,l and 7.5-9)	l≥ 230mm AQL<4.0,S2	☐	☐			
Chemical Resistance							
Penetration resistance to viral	ASTM F1671	Compliant	☐	☐			

COVID-19 Technical Specifications for Personal Protective Equipment and Related IPC supplies

Standard Test Title	Reference Standard	Minimum acceptable performance level	Compliant		Claimed performance (Class, Type, or measured)	Year/Version of standard	Reference document (.pdf)
			YES	No			
Permeation by continuous contact	ASTM F739	Compliant	☐	☐			
Permeation by intermittent contact	ASTM F1383	Compliant	☐	☐			
Human Repeat Insult Patch Testing - Allergens	ASTM D6355	Compliant	☐	☐			
Resistance to Chemotherapy Drugs	ASTM D6978	Compliant	☐	☐			
Primary skin irritation	ISO 10993	Compliant	☐	☐			
Skin sensitization	ISO 10993	Compliant	☐	☐			
Other							
shelf life*		5 years	☐	☐			
Quality compliance							
General quality management system	ISO 9001	Compliant	☐	☐			

COVID-19 Technical Specifications for Personal Protective Equipment and Related IPC supplies

Standard Test Title	Reference Standard	Minimum acceptable performance level	Compliant		Claimed performance (Class, Type, or measured)	Year/Version of standard	Reference document (.pdf)
			YES	No			
Medical device quality management	ISO 13485	Compliant	☐	☐			
Sampling procedures for inspection by attribute, post shipment	ISO 2859	Compliant	☐	☐			
Regulatory clearance							
EU PPE Regulation 2016/425		Valid, issued <5 years	☐	☐			
EN MD Directive 93/42/EEC		Valid, issued <5 years	☐	☐			
US FDA 510(k)		Valid, issued <5 years	☐	☐			
NMPA, export		Valid, issued <5 years	☐	☐			
NMPA, internal		Valid, issued <5 years	☐	☐			

COVID-19 Technical Specifications for Personal Protective Equipment and Related IPC supplies

COVID-19 Technical Specifications for Personal Protective Equipment and Related IPC supplies

Technical compliance to relevant performance standards for surgical gloves (sterile)

Supplier:

Manufacturer: Full Product Description:

Model Name: Size:

Standard Test Title	Reference Standard	Minimum acceptable performance level	Compliant		Claimed performance (Class, Type, or measured)	Year/Version of standard	Reference document (.pdf)
			YES	No			
Test report origin							
ILAC accredited lab	ISO 17025	Compliant	☐	☐			
National Notifying Body	ISO 17025	Compliant	☐	☐			
Local, non-accredited	ISO 17025	Compliant	☐	☐			
Whole glove performance							
Standard Specification for Rubber Examination Gloves	ASTM D3577	Type 1 (natural)	☐	☐			
		Type 2 (synthetic)	☐	☐			
Terminology and performance requirements for chemical risks	EN ISO 374-1	Type A	☐	☐			
		Type B	☐	☐			

COVID-19 Technical Specifications for Personal Protective Equipment and Related IPC supplies

Standard Test Title	Reference Standard	Minimum acceptable performance level	Compliant		Claimed performance (Class, Type, or measured)	Year/Version of standard	Reference document (.pdf)
			YES	No			
		Type C	☐	☐			
Determination of resistance to penetration	EN ISO 374-2	Compliant	☐	☐			
Determination of resistance to degradation by chemicals	EN ISO 374-4	Compliant	☐	☐			
Terminology and performance requirements for micro-organisms risks	EN ISO 374-5	Compliant	☐	☐			
Medical gloves for single use - Part 1: Requirements and testing for freedom from holes	EN 455-1	Compliant	☐	☐			
Medical gloves for single use - Part 2: Requirements and testing for physical properties	EN 455-2	Compliant	☐	☐			
Medical gloves for single use - Part 3: Requirements and testing for biological evaluation	EN 455-3	Compliant	☐	☐			

COVID-19 Technical Specifications for Personal Protective Equipment and Related IPC supplies

Standard Test Title	Reference Standard	Minimum acceptable performance level	Compliant		Claimed performance (Class, Type, or measured)	Year/Version of standard	Reference document (.pdf)
			YES	No			
Medical gloves for single use - Part 4: Requirements and testing for shelf life determination	EN 455-4	Compliant	☐	☐			
Penetration/ Freedom from holes							
Water test	ASTM D3577	AQL < 1.5	☐	☐			
Water tightness test	EN 455-1	AQL < 1.5	☐	☐			
Water leak/Air leak test	EN ISO 374-2 (ISO 2895)	Level 3 AQL <0.65	☐	☐			
		Level 2 AQL <1.50	☐	☐			
		Level 1 AQL <4.50	☐	☐			
Material strength characteristics							
Tensile strength (before aging)		Compliant	☐	☐			
Ultimate elongation (before aging)		Compliant	☐	☐			

COVID-19 Technical Specifications for Personal Protective Equipment and Related IPC supplies

Standard Test Title	Reference Standard	Minimum acceptable performance level	Compliant		Claimed performance (Class, Type, or measured)	Year/Version of standard	Reference document (.pdf)
			YES	No			
Stress at 500% elongation (before aging)	ASTM D3577 (Type 1)	Compliant	☐	☐			
Tensile strength (after aging)		Compliant	☐	☐			
Ultimate elongation (after aging)		Compliant	☐	☐			
Tensile strength (before aging)	ASTM D3577 (Type 2)	Compliant	☐	☐			
Ultimate elongation (before aging)		Compliant	☐	☐			
Stress at 500% elongation (before aging)		Compliant	☐	☐			
Tensile strength (after aging)		Compliant	☐	☐			
Ultimate elongation (after aging)		Compliant	☐	☐			
Breaking force (before aging)	EN 455-2	Compliant	☐	☐			
Breaking force (after aging)		Compliant	☐	☐			
Powder residue							
Powder free	ASTM D3577	<2.0mg (N=5)	☐	☐			

COVID-19 Technical Specifications for Personal Protective Equipment and Related IPC supplies

Standard Test Title	Reference Standard	Minimum acceptable performance level	Compliant		Claimed performance (Class, Type, or measured)	Year/Version of standard	Reference document (.pdf)
			YES	No			
Powder free	EN 455-3	<2.0mg	☐	☐			
Powdered	ASTM D3577	max 10 mg/dm2 (N=2)	☐	☐			
Powdered	EN 455-3	>2.0mg	☐	☐			
Protein content for allergies							
Aqueous soluble protein content	ASTM D3577	<200 µg/dm2 (N=3)	☐	☐			
	EN 455-3	<10 µg protein per g of glove	☐	☐			
Extractable antigenic protein content	ASTM D3577	<10 µg/dm2 (N=1)	☐	☐			
Size							
Thickness / Length / Width	ASTM D3577	Compliant	☐	☐			
		Compliant	☐	☐			
		Compliant	☐	☐			

COVID-19 Technical Specifications for Personal Protective Equipment and Related IPC supplies

Standard Test Title	Reference Standard	Minimum acceptable performance level	Compliant		Claimed performance (Class, Type, or measured)	Year/Version of standard	Reference document (.pdf)
			YES	No			
	EN 455	Compliant	☐	☐			
Chemical Resistance							
Penetration resistance to viral	ASTM F1671	Compliant	☐	☐			
Permeation by continuous contact	ASTM F739	Compliant	☐	☐			
Permeation by intermittent contact	ASTM F1383	Compliant	☐	☐			
Human Repeat Insult Patch Testing - Allergens	ASTM D6355	Compliant	☐	☐			
Resistance to Chemotherapy Drugs	ASTM D6978	Compliant	☐	☐			
Primary skin irritation	ISO 10993	Compliant	☐	☐			
Skin sensitization	ISO 10993	Compliant	☐	☐			
Sterility test							
the latest edition of the U.S. Pharmacopeia	ASTM D3577	Compliant	☐	☐			

COVID-19 Technical Specifications for Personal Protective Equipment and Related IPC supplies

Standard Test Title	Reference Standard	Minimum acceptable performance level	Compliant		Claimed performance (Class, Type, or measured)	Year/Version of standard	Reference document (.pdf)
			YES	No			
Sterile barrier integrity	EN ISO 11607	Compliant	☐	☐			
Other							
shelf life*		5 years	☐	☐			
Quality compliance							
General quality management system	ISO 9001	Compliant	☐	☐			
Medical device quality management	ISO 13485	Compliant	☐	☐			
Sampling procedures for inspection by attribute, post shipment	ISO 2859	Compliant	☐	☐			
Regulatory clearance							
EU PPE Regulation 2016/425		Valid, issued <5 years	☐	☐			

COVID-19 Technical Specifications for Personal Protective Equipment and Related IPC supplies

Standard Test Title	Reference Standard	Minimum acceptable performance level	Compliant		Claimed performance (Class, Type, or measured)	Year/Version of standard	Reference document (.pdf)
			YES	No			
EN MD Directive 93/42/EEC		Valid, issued <5 years	☐	☐			
US FDA 510(k)		Valid, issued <5 years	☐	☐			
NMPA, export		Valid, issued <5 years	☐	☐			
NMPA, internal		Valid, issued <5 years	☐	☐			

COVID-19 Technical Specifications for Personal Protective Equipment and Related IPC supplies

Technical compliance to relevant performance standards – Isolation or surgical gowns

Supplier:

Manufacturer:

Model:

Standard Test Title	Reference Standard	Minimum acceptable performance level	Compliant		Claimed performance (Class, Type, or measured)	Year/Version of standard	Reference document (.pdf)
			YES	No			
Test report origin							
ILAC accredited lab	ISO 17025	Compliant	☐	☐			
National Notifying Body	ISO 17025	Compliant	☐	☐			
Local, non-accredited	ISO 17025	Compliant	☐	☐			
Whole gown performance, surgical							
Liquid barrier performance	AAMI PB70	Level 1	☐	☐			
Liquid barrier performance	AAMI PB70	Level 2	☐	☐			

COVID-19 Technical Specifications for Personal Protective Equipment and Related IPC supplies

Standard Test Title	Reference Standard	Minimum acceptable performance level	Compliant		Claimed performance (Class, Type, or measured)	Year/Version of standard	Reference document (.pdf)
			YES	No			
Liquid barrier performance	AAMI PB70	Level 3	☐	☐			
Liquid barrier performance	AAMI PB70	Level 4	☐	☐			
Surgical clothing and drapes	EN 13795	Standard Performance	☐	☐			
Surgical clothing and drapes	EN 13795	High Performance	☐	☐			
Protective clothing against liquid chemicals	EN 13034	Compliant	☐	☐	**Hydrostatic head pressure: cm of H2O**		
Surgical gowns	YY/T 0506	Compliant	☐	☐			
Sterilization of medical devices	EN 556	Compliant (sterile)	☐	☐			
Whole gown performance, isolation							

COVID-19 Technical Specifications for Personal Protective Equipment and Related IPC supplies

Standard Test Title	Reference Standard	Minimum acceptable performance level	Compliant		Claimed performance (Class, Type, or measured)	Year/Version of standard	Reference document (.pdf)
			YES	No			
Isolation gowns	ASTM F3352	Compliant	☐	☐			
Protective clothing against liquid chemicals	EN 13034	Compliant	☐	☐			
Material performance							
Water resistance (impact penetration)	AATCC 42	<4.5 g (AAMI Level 1) AQL 4%, RQL=20%	☐	☐			
		≤ 1.0 g (AAMI Level 2) AQL 4%, RQL=20%	☐	☐			
Water resistance (hydrostatic pressure)	AATCC 127	≥ 20 cm (AAMI Level 2) AQL 4%, RQL=20%	☐	☐			

COVID-19 Technical Specifications for Personal Protective Equipment and Related IPC supplies

Standard Test Title	Reference Standard	Minimum acceptable performance level	Compliant		Claimed performance (Class, Type, or measured)	Year/Version of standard	Reference document (.pdf)
			YES	No			
		≥ 20 cm (AAMI Level 3) AQL 4%, RQL=20%	☐	☐			
Viral penetration	ASTM F1671	Pass (AQL 4%, RQL=20% (AAMI Level 4)	☐	☐			
Clothing for protection against contact with blood and body fluids	ISO 16604	Class 5	☐	☐			
Resistance to wet bacterial penetration	ISO 22610	≥ 2.8 I_B (critical area, std performance)	☐	☐			
		≥ 6.0 I_B (critical area, std performance)	☐	☐			
Resistance to dry microbial penetration	ISO 22612	≤ 300 CFU	☐	☐			

COVID-19 Technical Specifications for Personal Protective Equipment and Related IPC supplies

Standard Test Title	Reference Standard	Minimum acceptable performance level	Compliant		Claimed performance (Class, Type, or measured)	Year/Version of standard	Reference document (.pdf)
			YES	No			
Cleanliness microbial / Bioburden	EN ISO 11737-1	≤ 300 CFU/ 100 cm^2	☐	☐			
Particle release	EN ISO 9073-10	≤ 4.0 log_{10} (lint count)	☐	☐			
Liquid penetration	EN ISO 811	≥ 20 cm H2O (critical area, std performance)	☐	☐			
		≥ 10 cm H2O (less critical area, std performance)	☐	☐			
		≥ 100 cm H2O (critical area, high performance)	☐	☐			
		≥ 10 cm H2O (less critical area, high performance)	☐	☐			
Physical performance/characteristics							

COVID-19 Technical Specifications for Personal Protective Equipment and Related IPC supplies

Standard Test Title	Reference Standard	Minimum acceptable performance level	Compliant		Claimed performance (Class, Type, or measured)	Year/Version of standard	Reference document (.pdf)
			YES	No			
Seam type	**N/A**	Stitched, welded, taped	☐	☐			
Bursting strength (Wet)	EN ISO 13938-1	≥ 40 kPa (critical area)	☐	☐			
Tensile strength (Dry)	EN 29073-3	≥ 20 N (critical and less critical areas)	☐	☐			
Tensile strength (Wet)	EN 29073-3	≥ 20 N (critical area)	☐	☐			
Basis weigh	ASTM D3776	-	☐	☐			
Shelf life		5 years	☐	☐			
Quality compliance							
General quality management system	ISO 9001	Compliant	☐	☐			

COVID-19 Technical Specifications for Personal Protective Equipment and Related IPC supplies

Standard Test Title	Reference Standard	Minimum acceptable performance level	Compliant		Claimed performance (Class, Type, or measured)	Year/Version of standard	Reference document (.pdf)
			YES	No			
Medical device quality management	ISO 13485	Compliant	☐	☐			
Sampling procedures for inspection by attribute, post shipment	ISO 2859	Compliant	☐	☐			
Regulatory clearance							
EU PPE Regulation 2016/425		Valid, issued <5 years	☐	☐			
EN MD Directive 93/42/EEC		Valid, issued <5 years	☐	☐			
US FDA 510(k)		Valid, issued <5 years	☐	☐			
NMPA, export clearance		Valid, issued <5 years	☐	☐			

COVID-19 Technical Specifications for Personal Protective Equipment and Related IPC supplies

Standard Test Title	Reference Standard	Minimum acceptable performance level	Compliant		Claimed performance (Class, Type, or measured)	Year/Version of standard	Reference document (.pdf)
			YES	No			
NMPA, internal use		Valid, issued <5 years	☐	☐			
Other:		Valid, issued <5 years	☐	☐			