Technical specifications of personal protective equipment for COVID-19

INTERIM GUIDANCE

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Contents

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Abbreviations

AQL	acceptance quality limit
CE	Conformité Européenne
CFU	colony forming unit
EU	European Union
FDA	Food and Drug Administration (USA)
FSC	free sales certificate
IB	barrier index
ILAC	International Laboratory Accreditation Cooperation
IPC	infection prevention and control
ISO	International Organization for Standardization
NIOSH	National Institute for Occupational Safety and Health (USA)
NMPA	National Medical Products Administration (China)
OSHA	Occupational Safety and Health Administration (USA)
PPE	personal protective equipment
RQL	rejectable quality limit
TAG PPE	Technical Advisory Group of Experts on Personal Protective Equipment
WHO	World Health Organization

1. Methodology

Each personal protective equipment (PPE) item listed is considered a priority medical device for COVID-19 *(1)*. The technical specifications define the minimum requirements for the product to ensure good quality, safety and efficacy. The methods used to develop the following technical specifications involved review of the infection prevention and control (IPC) COVID-19 guidelines, review of PPE products available in the market, and PPE products approved by stringent regulatory agencies, and analysis of international, regional and country standards on PPE. The four COVID-19 guidelines analysed were: Rational use of personal protective equipment for coronavirus disease (COVID-19) and considerations during severe shortage *(2)*, Advice on the use of masks in the context of COVID-19 – in the community, during home care, and in health care settings *(3)*, COVID-19 advice for the public: when and how to use masks *(4)*, Analysis of the PPE required to perform the clinical management of COVID-19 patients *(5)*, and the Disease commodity package for novel coronavirus *(6)*.

The specifications were reviewed by members of the Technical Advisory Group of experts on Personal Protective Equipment (TAG PPE), who also provided technical input; and by WHO staff and consultants from WHO regional offices. All experts and consultants provided Conflict of Interest declarations and no conflicts were found.

2. Context and considerations

The present publication defines the basic technical characteristics of PPE. The decision as to the appropriate clinical use of each of these devices is reserved to medical staff and according to IPC guidance.

3. Regulatory approvals and certifications

For all the PPE and related IPC supplies the following regulatory approvals and certifications apply.

It should be noted that in some economic regions, some PPE is considered a medical device and therefore the relevant regulations are to be followed. In other regions, some PPE may be considered an industrial protection garment and not tagged for medical use.

Due to limited manufacturing capacity some products might come from other economic regions or might have "emergency use authorizations" from regulatory agencies. Therefore, the requirements listed below might apply only to the COVID-19 period and may be updated; otherwise, they will be valid for up to 2 years following publication.

Naming	Names, synonym
General technical requirements	See Section 4 for technical specifications for PPE specific for COVID-19.
Primary packaging	Labelling on the primary packaging needs to include: Name and/or trademark of the manufacturer. Model or product 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 non-medical devices). European Union (EU) Module C2 or D conformity to type certificate (Category 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). Proof of regulatory compliance, as appropriate, per the product's risk classification (e.g. Europe: Conformité Européenne [CE] certification and declaration of conformity and/or EU type examination certificate as applicable, e.g. PPE cat. III for respirators; USA: Food and Drug Administration [FDA] approval or emergency use authorization; China: National Medical Products Administration [NMPA] listed). Ability for purchaser to check authenticity directly with the issuing regulatory authority (e.g. online database of active licences). Category I PPE, may accept self-declaration with declaration of conformity (COVID-19 context). Authorized representative must be identified and document expiration date supplied (valid until).
Test reports	Official test reports (all pages, in English) must either originate from accredited test labs, whereby the accreditation authority is preferably a member of International Laboratory Accreditation Cooperation (ILAC), 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 test report(s) and 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).

4. Technical specifications for procurement

Item	Characteristics	Performance standards (or alternative equivalent standard)
Gloves, medical examination (non-sterile)	Gloves, examination, nitrile (preferable), latex, polychloroprene or PVC, powder-free, non-sterile (e.g. minimum 230 mm total length). Minimum thickness 0.05 mm. 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 0.10 mm. 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 reusable (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 resistant (preferable). Completely cover the sides and length of the face. May be reusable (made of robust material which can be cleaned and disinfected) or disposable.	EN 166 (if reusable) ANSI/ISEA Z87.1 (if reusable) Or alternative equivalent set of standards
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

Item	Characteristics	Performance standards (or alternative equivalent standard)
Mask, medical for health care 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.	
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/m^2. Thickness: 200–300 µm, 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) ASTM F903 for bleach, sodium hypochlorite EN 343 for waterproofing 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 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. Colour: white. Material: polyethylene (PE) or biodegradable or compostable material. Size: 85 x 145 cm (w x l) (± 15%). Thickness: not less than: 50 µm. Can resist water and disinfectant (ethanol 70% and chlorine solution 0.05% or 500 ppm).	Product performance testing if biodegradable • EN 13432 • ASTM D6400 • Or alternative equivalent set of standards
Gown, isolation	Single use, disposable, made of non-woven material, length mid-calf. Sizes S, M, L, XL. 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.	AAMI PB70 (Level 1–3) and ASTM F3352 EN 13034 - Type PB [6] (stitched gown), with minimum hydrostatic head of 50 cmH_2O AAMI PB70 Level 4 and ASTM F3352 or ISO 16604 Class 5 Or alternative equivalent set of standards

Item	Characteristics	Performance standards (or alternative equivalent standard)
Gown, surgical	Single use, disposable, non-woven 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 cmH_2O YY/T 0506 or alternative equivalent set of standards EN 556, if sterile, or alternative equivalent set of standards
Alcohol-based hand rub	Bottle 100 mL and 500 mL, at least 80% ethanol or 75% isopropyl alcohol (v/v).	ASTM E2755 EN 1500 Or alternative equivalent set of standards Optional: ASTM E1115 or ASTM E1174
Biohazard 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 °C). 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 20 L or 50 L. Thickness: minimum 0.038 mm (1.5 mil). 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°C
Safety box	Safety box for needles/syringes, 5 L capacity, cardboard for incineration, box of 25.	Biohazard label as per WHO PQS E010/011
Soap	Liquid (preferred), powder and bar.	
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 500 ppm). Material thickness, at level of the fingers, not less than: 0.38 mm. Length not less than: 30 cm. 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	50–100 m roll.	
Chlorine	NaDCC, granules, 1 kg, 65–70% + measurement spoon.	

References

1. WHO. List of priority medical devices for COVID-19 case management. Geneva: World Health Organization; 9 April 2020 (https://www.who.int/publications/m/item/list-of-priority-medical-devices-for-covid-19-case-management, accessed 30 October 2020).

2. WHO. Rational use of personal protective equipment for coronavirus disease (COVID-19) and considerations during severe shortages: interim guidance. Geneva: World Health Organization; 6 April 2020 (https://www.who.int/publications/i/item/rational-use-of-personal-protective-equipment-for-coronavirus-disease-(covid-19)-and-considerations-during-severe-shortages, accessed 30 October 2020).

3. WHO. Advice on the use of masks in the context of COVID-19: interim guidance; 5 June 2020 (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, accessed 30 October 2020).

4. WHO. Coronavirus disease (COVID-19) advice for the public: when and how to use masks; 20 October 2020 [website]. Geneva: World Health Organization; 2020 (https://www.who.int/emergencies/diseases/novel-coronavirus-2019/advice-for-public/when-and-how-to-use-masks, accessed 30 October, 2020).

5. WHO. Clinical management of COVID-19: interim guidance; 27 May 2020 (https://www.who.int/publications/i/item/clinical-management-of-covid-19, accessed 30 October 2020).

6. WHO. Disease commodity package for novel coronavirus. Geneva: World Health Organization; 11 January 2020 (https://www.who.int/publications/i/item/disease-commodity-package-for-novel-coronavirus, accessed 30 October 2020).

Selected further reading

AAMI (2020). AAMI offers free standards and resources to help fight coronavirus. Arlington (VA): Association for the Advancement of Medical Instrumentation (https://www.aami.org/detail-pages/press-release/aami-offers-free-standards-and-resources-to-help-fight-coronavirus, accessed 12 August 2020).

ASTM (2020). ASTM standards & COVID-19. West Conshohocken (PA): ASTM International (https://www.astm.org/COVID-19, accessed 12 August 2020).

BSI (2020). Personal protective equipment: COVID-19 response. London: British Standards Institution (https://www.bsigroup.com/en-GB/topics/novel-coronavirus-covid-19/medical-devices-ppe/, accessed 12 August 2020).

CDC (2020). Strategies for optimizing the supply of N95 respirators: crisis/alternate strategies. 28 June 2020. Atlanta (GA): Centers for Disease Control and Prevention (https://www.cdc.gov/coronavirus/2019-ncov/hcp/respirators-strategy/index.html, accessed 12 August 2020).

EU (2020). Commission recommendation (EU) 2020/403 of 13 March 2020. Luxembourg: Publications Office of the European Union (https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32020H0403, accessed 12 August 2020).

ISO (2020). COVID-19 freely available ISO standards. Geneva: International Organization for Standardization (https://www.iso.org/covid19, accessed 12 August 2020).

PAHO (2020). Technical and regulatory aspects of the extended use, reuse, and reprocessing of respirators during shortages, 10 June 2020. Washington (DC): Pan American Health Organization (https://iris.paho.org/handle/10665.2/52431, accessed 12 August 2020).

Standardization Administration of China (various dates). Beijing, China. Translated Chinese standards: ftp://ftp.cencenelec.eu/EN/COVID19/ENGTranslationsOfChineseStandards_Q4.1.zip

WHO (2020). Priority Medical Devices for COVID-19 [website]. Geneva: World Health Organization (https://www.who.int/medical_devices/priority/COVID-19/en/, accessed 17 August 2020).

WHO (2020). Technical Specification for Medical Devices [website]. Geneva: World Health Organization (https://www.who.int/medical_devices/management_use/mde_tech_spec/en/, accessed 18 May 2020).

Annex 1.
Tables of standards and values: respirators; medical face masks; isolation and surgical gowns; medical examination gloves (non-sterile); surgical gloves (sterile) (not exhaustive)

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)
Filtration (paraffin oil)	≥ 94% (FFP2)	N/A	N/A	N/A
Breathing resistance (inhalation)	≤ 70 Pa (@ 30 L/min) ≤ 240 Pa (@ 95 L/min) ≤ 500 Pa (clogging)	≤ 343 Pa (@ 85 L/min)	≤ 350 Pa (@ 85 L/min)	≤ 343 Pa (@ 85 L/min)
Breathing resistance (exhalation)	≤ 300 Pa (@160 L/min)	≤ 245 Pa (@ 85 L/min)	≤ 250 Pa (@ 85 L/min)	
Fit	Tested with 10 human participants, see below	Fit testing upon arrival according to OSHA, not required by NIOSH	10 participants, see below	Fit factor of 100, with 8 subjects
Total inward leakage	≤ 8% leakage (arithmetic mean)	N/A	≤ 8% leakage (arithmetic mean)	
CO_2 of inhalation air	≤ 1%	N/A	≤ 1%	
Synthetic blood penetration	If type IIR, 120 mmHg (≥ 29/32 passing masks	If surgical N95, 120 mmHg (≥ 29/32 passing masks)	None	If surgical N95, 120 mmHg (5 masks)

Medical face masks				
	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/cm^2)	< 40 (Type I, II) < 60 (Type IIR)	< 49 Pa or 5 mm H_2O/cm^2 (Level 1) < 58.8 Pa or 6 mm H_2O/cm^2 (Level 2, 3)	< 49	< 49
Synthetic blood penetration (kPa)	120 mmHg (ISO 22609)	80 mmHg or 10.7 kPa (Level 1)	120 mmHg or 16 kPa	N/A
Microbial cleanliness (CFU/g)	16 kPa (Type IIR)	120 mmHg or 16 kPa (Level 2) 160 mmHg or 21.4 kPa (Level 3)		
Total inward leakage	≤ 30	N/A	≤ 100	≤ 100

Isolation and surgical gowns			
	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, 3) (AQL 4%, RQL = 20%	
Water resistance (hydrostatic pressure)	≥ 20 cmH_2O (critical area, standard performance) ≥ 100 cmH_2O (critical area, high performance) ≥ 10 cmH_2O (less critical area, standard and high performance)	≥ 20 cm (AAMI Level 2) ≥ 50 cm (AAMI Level 3) (AQL 4%, RQL = 20%	≥ 20 cmH_2O (critical area, standard performance) ≥ 100 cmH_2O (critical area, high performance) ≥ 10 cmH_2O (less critical area, standard and high performance)
Viral penetration		Pass (AQL 4%, RQL = 20% (AAMI Level 4)	
Resistance to wet bacterial penetration	≤ 2.8 IB (critical areas, standard performance) ≤ 6.0 IB (critical areas, high performance)		≤ 2.8 IB (critical areas, standard performance) ≤ 6.0 IB (critical areas, high performance)
Resistance to dry microbial penetration	≤ 300 CFU (less critical areas, standard and high performance)		≤ 300 CFU (less critical areas, standard and high performance)
Cleanliness microbial	≤ 300 CFU (all areas, standard and high performance)		≤ 300 CFU (all areas, standard and high performance)
Bursting strength (dry)	≥ 40 kPa (all areas, standard and high performance)		≥ 40 kPa (all areas, standard and high performance)
Bursting strength (wet)	≥ 40 kPa (critical areas, standard and high performance)		≥ 40 kPa (critical areas, standard and high performance)
Tensile strength (dry)	≥ 20 N (all areas, standard and high performance)	≥ 30 N	≥ 20 N (all areas, standard and high performance)
Tensile strength (wet)	≥ 20 N (critical areas, standard and high performance)		≥ 20 N (critical areas, standard and high performance)
Other criteria to consider		Optional: • water vapour transmission rate (ASTM D6701) • evaporative resistance (ASTM F1868, Part B)	China (GB 38462) gown standard, in effect October 2020

Medical examination gloves (non-sterile)		
	Europe (EN 455) EN 455-1, EN 455-2, EN 455-3, EN 455-4	US (ASTM material specific) 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 ageing)	AQL N/A Nitrile > 6.0 N Latex (natural) > 6.0 N Polyisoprene > 6.0 N Polychloroprene > 6.0 N PVC, PE > 3.6 N	AQL < 4.0 (ISO 2859) Nitrile > 14 MPa Latex (natural) > 14 MPa Polychloroprene > 14 MPa PVC > 11 MPa
Powder residue content	< 2.0 mg	< 2.0 mg
Aqueous soluble protein content	<10 µg per g of glove	< 200 $\mu g/dm^2$
Extractable antigenic protein content	<10 µg per g of glove	< 10 $\mu g/dm^2$

Surgical gloves (sterile)		
	Europe (EN 455) EN 455-1, EN 455-2, EN 455-3, EN 455-4	US (ASTM material specific) D3577
Freedom from holes	AQL < 1.5 (ISO 2859)	AQL < 1.5 (ISO 2859)
Force at break (N)/ tensile strength (MPa) (after ageing)	AQL N/A All materials > 9.0 N	AQL < 4.0 (ISO 2859) Type 1 latex (natural) > 18 MPa Type 2 polyisoprene, polychloroprene, nitrile > 12 MPa
Powder residue content	< 2.0 mg	< 2.0 mg
Aqueous soluble protein content	< 10 µg per g of glove	< 200 µg/dm^2
Extractable antigenic protein content	< 10 µg per g of glove	< 10 µg/dm^2
Sterility	ASTM refers to United States Pharmacopeia pass/fail EN 455 refers to EN ISO 11607	

Annex 2.
Checklists: respirators; medical face masks; isolation and surgical gowns; medical examination gloves (non-sterile); surgical gloves (sterile)

Technical compliance to relevant performance standards for respirators (face filtering)

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 respirator performance							
Europe respirators	EN 149	FFP2					
	EN 149	FFP3					
United States respirators	NIOSH	N95					
	NIOSH	N99					
	NIOSH	N100					
	NIOSH	Surgical N95					
Republic of Korea respirators	KMOEL - 2017-64	1st Class					

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			
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)					
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)					
CO_2 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 (FFP2 with fluid resistance)	ISO 22609	120 mmHg					
Synthetic blood penetration	GB 19083	80 mmHg					
Synthetic blood penetration	GB 19083 (Grade 1), reference (YY/T 0691-2008)	Need test reference					

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	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) 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)					
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 (inhalation) @ 30 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					

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	GB2626, KN95	Max 350 Pa					
Breathing resistance (exhalation) @ 85 L/min	GB2626, KN95	Max 210 Pa					
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 licence	US FDA database	Active					
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					

Technical compliance to relevant performance standards for medical face mask

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					
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%					
Droplet filtration efficiency (3.0 µm particle size)	YY 0469	95% AQL 4%, RQL = 20%					
	YY 0469	80 mmHg AQL 4%, RQL = 20%					

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/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%					
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 mmH_2O/cm^2, 29.4 Pa/cm^2					
		< 4.0 mmH_2O/cm^2, 39.2 Pa/cm^2					
		< 5.0 mmH_2O/cm^2, 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					

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			
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					
NMPA, internal use		Valid, issued < 5 years					

Technical compliance to relevant performance standards for isolation and 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					
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: cmH_2O		
Surgical gowns	YY/T 0506	Compliant					
Sterilization of medical devices	EN 556	Compliant (sterile)					
Whole gown performance, isolation							
Isolation gowns	ASTM F3352	Compliant					
Protective clothing against liquid chemicals	EN 13034	Compliant					

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			
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%					
		≥ 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 IB (critical area, standard performance)					
		≥ 6.0 IB (critical area, standard performance)					
Resistance to dry microbial penetration	ISO 22612	≤ 300 CFU					
Cleanliness microbial/ bioburden	EN ISO 11737-1	≤ 300 CFU/100 cm^2					
Particle release	EN ISO 9073-10	≤ 4.0 log10 (lint count)					
Liquid penetration	EN ISO 811	≥ 20 cmH_2O (critical area, standard performance)					
		≥ 10 cmH_2O (less critical area, standard performance)					
		≥ 100 cmH_2O (critical area, high performance)					
		≥ 10 cmH_2O (less critical area, high performance)					

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			
Physical performance/characteristics							
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					
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					
NMPA, internal use		Valid, issued < 5 years					
Other:		Valid, issued < 5 years					

Technical compliance to relevant performance standards for medical 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 requirements for chemical risks	EN ISO 374-1	Type A					
		Type B					
		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					

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 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					
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					
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 ageing)	ASTM D6319	> 14 MPa AQL < 4.0, S2					
Tensile strength (after ageing)		> 14 MPa AQL < 4.0, S2					
Elongation (before ageing)		> 500% AQL < 4.0, S2					
Elongation (after ageing)		> 400% AQL < 4.0, S2					
Breaking force (before ageing)	EN 455-2	> 6.0 N					
Breaking force (after ageing)		> 6.0 N					

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 residue							
Powder free	ASTM D6319	< 2.0 mg (N = 5)					
Powder free	EN 455-3	< 2.0 mg					
Size							
Thickness	ASTM D6319	Finger > 0.05 mm AQL < 4.0, S2					
		Palm > 0.05 mm AQL < 4.0, S2					
	EN 455	N/A					
Length	EN 455-2 (all sizes)	≥ 240 mm					
	ASTM D6319 (xs, s and 6–7)	≥ 220 mm AQL < 4.0, S2					
	ASTM D6319 (uni, m, l and 7.5–9)	≥ 230 mm AQL < 4.0, S2					
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					

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			
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					
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					

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					
		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					

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 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					
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 ageing)	ASTM D3577 (Type 1)	Compliant					
Ultimate elongation (before ageing)		Compliant					
Stress at 500% elongation (before ageing)		Compliant					
Tensile strength (after ageing)		Compliant					
Ultimate elongation (after ageing)		Compliant					

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			
Tensile strength (before ageing)	ASTM D3577 (Type 2)	Compliant					
Ultimate elongation (before ageing)		Compliant					
Stress at 500% elongation (before ageing)		Compliant					
Tensile strength (after ageing)		Compliant					
Ultimate elongation (after ageing)		Compliant					
Breaking force (before ageing)	EN 455-2	Compliant					
Breaking force (after ageing)		Compliant					
Powder residue							
Powder free	ASTM D3577	< 2.0 mg (N = 5)					
Powder free	EN 455-3	<2.0 mg					
Protein content for allergies							
Aqueous soluble protein content	ASTM D3577	< 200 µg/dm^2 (N = 3)					
	EN 455-3	< 10 µg protein per g of glove					
Extractable antigenic protein content	ASTM D3577	< 10 µg/dm^2 (N = 1)					
Size							
Thickness/length/width	ASTM D3577	Compliant					
		Compliant					
		Compliant					
	EN 455	Compliant					

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			
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							
Latest edition of United States Pharmacopeia	ASTM D3577	Compliant					
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					

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			
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					

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