

Requirements for procurement of Personal Protective Equipment (PPE) in the context of the COVID-19 emergency

Version 2.0. Updated on 10 March 2021

ITEMS	REQUIREMENTS
<p>1. Product description</p>	<ul style="list-style-type: none"> • A description of the product(s) must be provided by the supplier. It must include: <ul style="list-style-type: none"> ○ brand or trade name, ○ model or product reference, ○ intended use, ○ a list of the materials used to manufacture the product, ○ expected lifetime, ○ approved storage conditions, ○ product sizes, ○ photographs of the product, including photographs of the packaging configuration (primary, secondary, and tertiary packaging), and ○ manufacturer information (company name, full address). <p><i>[NOTE: Information can be provided as part of a Catalog, Product Details, or equivalent].</i></p>
<p>2. Technical requirements</p>	<ul style="list-style-type: none"> • See Table 1 for COVID-19 technical specifications for PPE.
<p>3. Manufacturing information</p>	<ul style="list-style-type: none"> • A manufacturing site license issued according to the legislation of the country of origin. • Certified Quality Management System of each manufacturer site involved in the manufacturing process. <ul style="list-style-type: none"> ○ Certified quality management system for medical devices (e.g. ISO 13485) and application of risk management to medical devices (e.g. ISO 14971), if applicable. ○ 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).

<p>4. Regulatory compliance/certification</p>	<ul style="list-style-type: none"> • Proof of regulatory compliance, as appropriate, per the product’s risk classification in at least one of the International Medical Device Regulators Forum¹ (IMDRF) members. [NOTE 1: <i>Ability to check authenticity directly with the issuing regulatory authority (e.g. online database of active licenses)</i>]. <p>For example:</p> <ul style="list-style-type: none"> ○ <i>Europe:</i> Conformité Européenne [CE] certification and EU declaration of conformity and/or EU Type-Examination Certificate, as applicable according to product’s category. [NOTE 2: <i>Authorized representative must be identified, and document expiration date supplied (valid until)</i>]. <ul style="list-style-type: none"> ▪ For Category I PPE: May accept self-declaration with EU declaration of conformity only (COVID-19 context). ▪ For Category III PPE: EU Type-Examination Certificate (Module C2 or Module D) must also be submitted in addition to the other certifications. ○ <i>USA:</i> United States Food and Drug Administration [FDA] approval, 510(k) clearance, or emergency use authorization. ○ <i>China:</i> National Medical Products Administration [NMPA] listed.
<p>5. Test reports</p>	<ul style="list-style-type: none"> • 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. <ul style="list-style-type: none"> ○ 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. <p>NOTES:</p> <ol style="list-style-type: none"> 1. <i>Instructions for authentication of test report(s) and certificates should be provided.</i>

¹ Australia, *Therapeutic Goods Administration*; Brazil, *National Health Surveillance Agency (ANVISA)*; Canada, *Health Canada*; China, *National Medical Products Administration*; European Union, *European Commission Directorate and Member States*; Japan, *Pharmaceuticals and Medical Devices Agency and the Ministry of Health, Labour and Welfare*; Russia, *Russian Ministry of Health*; Singapore, *Health Sciences Authority*; South Korea, *Ministry of Food and Drug Safety*; and United States of America, *US Food and Drug Administration*.

	<p>2. <i>Ability to check authenticity directly with the accredited test laboratory (e.g. online uploading of test report and automatic version check or emailing test facility).</i></p>
<p>6. Product labelling</p>	<ul style="list-style-type: none"> • The supplier must provide a copy of the product labelling (including primary, secondary, and tertiary packing). [NOTE: Documents must be in any of the official languages of the PAHO Region: English, Spanish, French and/or Portuguese] <ul style="list-style-type: none"> ○ Labelling must minimally include: a) brand or trade name, b) model or product reference, c) Lot/batch number d) manufacturer' contact information, e) recommendations that would reduce sufficiently the risk of use, f) intended use, g) handling measures for particular storage and transport conditions (temperature, pressure, light, humidity), h) warnings and precautions, i) Expiry date, and j) particular product conditions (e.g. sterility). ○ Instructions for use, where possible, should comply with the <i>principles of labelling for medical devices and IVD medical devices</i> of IMDRF/GRRP WG/N52 FINAL:2019

Right to share information with PAHO Member States

PAHO, at its sole discretion, may share with the corresponding National Regulatory Authorities from the recipient country, documents from the technical proposal or other documents and data requested for clarification or to resolve any potential claims or inquiries.

Disclaimer

This proposal was developed per emergency COVID-19 only and it does not replace current practices applied by PAHO to assess technical proposals of products procured by PAHO through regular bidding processes or request for quotations.

Above document does not include responsibilities of other stakeholders such as manufacturers, distributors, procurement agencies and health-care professionals, all of whom have roles in assuring the quality, safety, and performance of PPE.

Shipping documents must be developed according to PAHO experiences procuring PPE.

TABLE 1. COVID-19 TECHNICAL SPECIFICATIONS FOR PPE

PRODUCT	TECHNICAL DESCRIPTION	STANDARD
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 snugly 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.	<ul style="list-style-type: none"> · EN 166 · ANSI/ISEA Z87.1 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 noncritical zones. Reusable gowns should meet the minimum performance requirements after maximum suggested laundering cycles.	<ul style="list-style-type: none"> · AAMI PB70 (Level 1–3) and ASTM F3352 · EN 13034 - Type PB [6] (stitched gown), with minimum hydrostatic head of 50 cmH₂O · 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.	<ul style="list-style-type: none"> · AAMI PB70 and ASTM F2407 · EN 13795 · EN 13034 - Type PB [6] (stitched gown), with minimum hydrostatic head of 50 cmH₂O · YY/T 0506 or alternative equivalent set of standards · EN 556, if sterile, 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.	<ul style="list-style-type: none"> · EN 166 · ANSI/ISEA Z87.1 Or alternative equivalent set of standards

Gloves, medical examination (non-sterile)	<p>Gloves, examination, nitrile (preferable), latex, polychloroprene or PVC, powder-free, non-sterile. (e. g., minimum 230mm total length).</p> <p>Minimum thickness 0.05mm.</p> <p>Sizes S, M, L.</p>	<ul style="list-style-type: none"> · EN 455 · ASTM D6319, D3578, D5250, or D6977 · EN 374, optional additional <p>Or equivalent set of standards</p>
Gloves, surgical (sterile)	<p>Gloves, surgical, nitrile (preferable), latex, polyisoprene or polychloroprene, sterile, powder-free, single use.</p> <p>Gloves should have long cuffs, reaching well above the wrist, ideally to mid-forearm.</p> <p>Minimum thickness 0.10 mm.</p> <p>Sizes ranging 5.0–9.0.</p>	<ul style="list-style-type: none"> · EN 455 · ASTM D3577 <p>Sterility:</p> <ul style="list-style-type: none"> · United States Pharmacopeia · EN ISO 11607 · Or alternative equivalent set of standards
Mask, medical for health care worker	<p>Medical mask, good breathability, internal and external faces should be clearly identified, 98% droplet filtration, preferably fluid resistance.</p>	<p>Fluid resistant masks (surgical masks):</p> <ul style="list-style-type: none"> · EN 14683 Type IIR, · ASTM F2100 Level 1, 2 or 3, · YY 0469, with at least 98% bacterial droplet filtration · Or alternative equivalent standard <p>Non-fluid resistant mask:</p> <ul style="list-style-type: none"> · EN 14683 Type II · YY/T 0969, with at least 98% bacterial droplet filtration · Or alternative equivalent standard
Mask, medical for patient	<p>Medical mask, good breathability, internal and external faces should be clearly identified.</p>	<ul style="list-style-type: none"> · EN 14683 Type I, · YY 0469 or YY/T 0969, if bacterial droplet filtration is below 98% <p>Or alternative equivalent standard.</p>
Particulate respirator	<p>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).</p>	<p>Fluid resistant respirator:</p> <ul style="list-style-type: none"> · 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

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| | | <p>Non-fluid resistant respirator:</p> <ul style="list-style-type: none">· Minimum NIOSH approved "N95" according to 42 CFR Part 84· EN 149, minimum "FFP2"· GB 2626, minimum "KN95"· Or alternative equivalent set of standards |
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Source: These technical requirements were extracted from the *Technical specifications of personal protective equipment for COVID-19* developed by the World Health Organization (WHO). Available at: https://www.who.int/publications/i/item/WHO-2019-nCoV-PPE_specifications-2020.1