

UNICEF TECHNICAL REQUIREMENTS FOR PERSONAL PROTECTIVE EQUIPMENT (PPE)

April 2020

A. Background

This document was developed for suppliers and products to comply with, in the context of UNICEF Quality Assurance (QA) Policy for procurement and supply. It adopts the guidance of the International Medical Device Regulators Forum (IMDRF)¹ to ensure safety performance, quality and equality in our procurement processes of medical devices, including personal protective equipment (PPE).

The Personal Protective equipment referred in this document is for protective clothing, gloves, face shields, goggles, facemasks and/or respirators or other equipment designed to protect the wearer from injury or the spread of infection or illness. Some products may appear to have a medical purpose, but their purpose for use is to protect the user. Such products are considered as PPE rather than medical devices.

All PPE intended for use as a medical device must meet specific performance standards for protection and be "Conformité Européene" (CE) marked as a medical device. For example: protective masks (e.g. from the environment) are not considered medical devices but PPE. However, a surgical masks used in an operating theatre to protect the user is considered a medical device.

B. Technical requirements framework

1. Conformity with Quality Management System (QMS) standards Suppliers²/Manufacturers shall conform to:

- a) ISO 9001:2015_Quality Management Systems - Requirements*, or,
- b) **For products classified as medical devices** conform to ISO 13485:2016 - Quality management systems- Requirements for regulatory purposes.

¹ The International Medical Device Regulators Forum (IMDRF) was conceived in February 2011, to build on the strong foundational work of the Global Harmonization Task Force on Medical Devices (GHTF) and to accelerate international medical device regulatory harmonization and convergence. IMDRF: <http://www.imdrf.org>. ² Entity that provides goods and/or services

* In case the ISO 9001 certification cannot be provided by manufacturer or in the process of being obtained, prior to long term agreement (LTA) award, UNICEF QMS auditors may visit supplier and manufacturing site including sub-contractors.

2. Conformity with production standards

- a. The manufacturer should hold the product technical documentation as per the IMDRF/GHTF requirements (goods that do not meet these standards shall not be acceptable to UNICEF):

SG1/N68:2012	Essential Principles of Safety and Performance of Medical Devices
SG1/N11:2008	Summary Technical Documentation (STED) for demonstrating conformity to the Essential Principles of Safety and Performance of Medical Devices
SG1/N77:2012	Principle of Medical Devices Classification
SG1/N70:2011	Label and Instructions for Use for Medical Devices


- b. The product(s) shall conform to the relevant International Organisation for Standardisation (ISO) standards for suppliers/manufacturers of medical devices and risk management.

- c. The labelling of the product shall meet the requirements as described in the below standards and guidance documents:

ISO 13688:2013	Protective clothing -General requirements
ASTM F 1301	Labelling of chemical protective clothing
ANSI Z535.4-1991	American National Standard for Product Safety Signs and Labels

- d. The product shall be assessed by at least one of the IMDRF regulatory authorities (or at minimum with SG1-N70:2011: Label and Instructions for Use for Medical Devices): The IMDRF Management Committee comprises regulatory authority representatives from the following jurisdictions:

- Australia, Therapeutic Goods Administration
- Brazil, National Health Surveillance Agency (ANVISA)
- Canada, Health Canada
- China, National Medical Products Administration
- European Union, European Commission Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs
- 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
- United States of America, US Food and Drug Administration

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- e. Any product registered for “Research Use Only” or “For export only” is not acceptable, unless specifically authorised in writing by UNICEF.

3. Product(s) compliance with regulatory requirements for marketing

approval

Product(s) shall be authorised for use by at least one of the Management Committee Members of the International Medical Device Regulators Forum (IMDRF)

N.B: "Where a device is intended by the manufacturer to be used in accordance with both the provisions on PPE Regulation (EU) 2016/425 and the MDD 93/42, the relevant basic health and safety requirements of PPE Regulation (EU) 2016/425 shall be fulfilled".

4. Product(s) documentation

- a. Product(s) shall conform to design, functionality, claimed intended use by the manufacturer and technical specifications as stated by UNICEF.
- b. UNICEF may ask for additional test reports for specific products deemed high risk in the context of the UNICEF scope of activities.

5. Product(s) shelf life

- a. The supplier shall provide the total product shelf life in months (as applicable).
- b. The successful the supplier shall ensure a minimum of two thirds of the shelf life remain at delivery. Products delivered with less than two thirds remaining shelf life are not acceptable to UNICEF.

6. Sterile products

- a. The supplier shall provide certificates issued by the manufacturer of all sterile products in accordance to the ISO 11135 and ISO 11137 (as applicable) - Sterilization of health care products
- b. The supplier shall provide batch release certificates for each batch delivered to UNICEF.

7. Hazardous goods

The supplier shall provide the material safety data sheet (MSDS) issued by the manufacturer as applicable, including section 14: Transport information, completed (as applicable).

8. Product(s) modifications

In case of a LTA award, suppliers shall notify to UNICEF any major product modification, such as brand name, marketing clearance or any approval certification.

9. Sustainability goals

As UNICEF moves towards the implementation of the Sustainable Developmental Goals, it is keenly interested in the efforts made by manufacturers and suppliers towards sustainable initiatives. Thus, as an asset, but not a requirement, the supplier is encourage to provide information on the implementation of sustainability in the production and distribution phases of the procurement process with an emphasis on social and environmental responsibilities.

C. Attachments that shall be submitted with the offer for each product

1.	QMS Standards	<p>a. Supplier: Valid ISO 9001 or ISO 13485 certificate (as applicable) including scope. Copy in English.</p> <p>b. Legal manufacturer: At least valid ISO 9001 certificate*. Copy in English. For products classified as medical devices, valid ISO 13485 certificate. Copy in English.</p> <p><i>*For body bags: in case the ISO 9001 certification cannot be provided by manufacturer or in the process of being obtained, prior to LTA award, UNICEF QMS auditors may visit supplier and manufacturing site including sub-contractors.</i></p>
2.	Product standards	As described in the technical product specifications.
3.	Marketing approval	<p>Valid certificate from one of the members of the IMDRF.</p> <p>The certificate shall indicate:</p> <p>a. Name of regulatory authority;</p> <p>b. Marketing clearance with licence number</p> <p><i>For medical devices used as PPE, both PPE Regulation (EU) 2016/425 and the MDD (Medical Devices Directive) 93/42 EEC apply.</i></p> <p><i>For PPE, only the PPE Regulation (EU) 2016/425 applies.</i></p>
4.	Product documentation	<p>a. Claimed product intended use.</p> <p>b. Supplier's product code (catalogue number) & short description;</p> <p>c. Manufacturer's product code (catalogue number) & short description;</p> <p>d. Supplier's contact details, including link to web site with product catalogue;</p> <p>e. Manufacturer's contact details, including link to web site with product catalogue;</p> <p>f. Contact details of the person appointed for post-market surveillance including vigilance, customer complaints and recalls.</p> <p>g. Complete technical product specification (technical data sheet);</p> <p>h. List of all supporting items/devices required, but not supplied;</p> <p>i. For sterile product: Sterilisation method and process (standard) followed for validation and routine control of sterilisation for medical devices; Date of sterilisation; Batch number (lot number); Batch quantity;</p> <p>j. Recommended temperature and humidity for shipping, storage and use/operating;</p> <p>k. Instructions for use (IFU), brochure and training material in English, French or Spanish;</p> <p>l. Estimated weight and volume;</p> <p>m. Photos of primary and secondary packaging with readable label information.</p>
5.	Product lot release	As described in the technical product specifications.
6.	Hazardous goods	Hazardous classification (including MSDS), as described in the technical product specifications
7.	Sustainability goals	Indicate the company's efforts to implement any of the following in the coming 12 months:



		<ul style="list-style-type: none">a. <u>Environmental management</u>: Plans to obtain the Environmental Management System certificate ISO 14001 or equivalent with CO₂ reduction targets. Specify which areas will be covered.b. <u>Energy Management</u>: Plans to obtain the Energy Management System certificate, ISO 50001. Specify which areas will be covered.c. <u>Social Accountability</u> : Plans to conform to the Standards of Social Accountability e.g. SA8000 or other standards that demonstrate commitment to sustainability issues. Specify which areas will be covered.d. <u>Global initiatives</u>: Plans to join the Global Reporting Initiative and/or the United Nations Global Compact.e. <u>Other related information</u>: Other plans related to sustainable production/distribution.
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SUPPLY DIVISION

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