UNICEF TECHNICAL REQUIREMENTS FOR MEDICAL DEVICES (MD) - GENERIC

January 2021

A. Background

UNICEF Technical requirements for Medical Devices are the requirements that suppliers need to comply with, and that products need to conform to, in the context of UNICEF's Quality Assurance (QA) Policy for procurement and supply. It adopts the guidance of the International Medical Device Regulators Forum (IMDRF)[1] to ensure safety, quality and equity in our procurement processes of medical devices.

B. Technical requirements for medical devices (MD)

1. Conformity with Quality Management System (QMS) standards

Suppliers[2]/Manufacturers shall conform to at least one of the following quality management system standards:

a. **For products classified as medical devices:**
Manufacturers: ISO13485 Quality management systems - Requirements for regulatory purposes.

b. **For other devices:** ISO 9001 Quality management systems – Requirements for regulatory purposes.

2. Product conformity to production standards

a. The technical documentation shall show that product(s) conform to the production requirements as described in the Global Harmonization Task Force (GHTF)[3] documents (goods that do not conform to these standards will not be acceptable to UNICEF):

SG1/N11:2008	Summary Technical Documentation (STED) for demonstrating conformity to the Essential Principles of Safety and Performance of Medical Devices
IMDRF/GRRP WG/N47 FINAL:2018	Essential Principles of Safety and Performance of Medical Devices and IVD Medical Devices
SG1/N77:2012	Principle of Medical Devices Classification

[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
[3] GHTF/IMDRF documents: http://www.imdrf.org/documents/documents.asp

b. The product(s) shall conform to the standards stipulated by the International Organisation for Standardisation (ISO) and/or equivalent standards as recognised by the IMDRF[1].

c. The labelling of the product shall meet the requirements described in the regulations of at least one of the 5 regulatory authorities listed below (or at a minimum with: IMDRF/GRRP WG/N52 FINAL:2019: Principles of Labelling for Medical Devices and IVD Medical Devices):

   1) Australia: Therapeutic Goods Administration (TGA);
   2) Canada: Health Canada;
   3) European Union: Regulatory agency in the European countries;
   4) Japan: Pharmaceuticals and Medical Devices Agency (PMDA)
   5) USA: Food and Drug Administration (FDA).

d. Any medical device registered for "Research Only" or "For export only" is not acceptable, unless specifically authorised in writing by UNICEF.

3. Product compliance with regulatory requirements for market clearance

Products shall be cleared by at least one of the 5 regulatory authorities mentioned above and comply with the corresponding market release certificates (listed below) as described in the GHTF for market clearance:

a. Australia: TGA Device Licence;
b. Canada: Device Licence;
c. European Union: CE 93/42 EEC Medical Devices Directive (MDD) Mark;
d. Japan: Device Licence;
e. USA: 510k market clearance.

N.B. – UNICEF is aware of the changes being implemented by the EU with regards to the Medical Devices and IVD Directives. As these changes take shape and the new Regulations are adopted and implemented by Notified Bodies and subsequently Certifying Bodies, UNICEF reserves the right to request information from current or future suppliers on how they plan to accommodate the changes so that appropriate ISO certification is maintained.

4. Product documentation

a. UNICEF shall ask for the WHO pre-qualification award letter if applicable.
b. Product(s) shall conform to the design, functionality and intended use stated by the manufacturer and the technical specifications stated by UNICEF.
c. Conform to international standards for product packaging and labelling;
d. Be delivered with the manufacturer's guidelines and /or instructions for use and maintenance. Manufacturer documentation shall be available at least in English, French and Spanish
e. UNICEF may ask for additional test reports for specific products deemed high risk in the context of UNICEF's scope of activities.

Note: Testing & calibration laboratories shall conform with ISO/IEC 17025:2017 General requirements for the competence of testing and calibration laboratories.

5. Product shelf life / life span

a. The supplier shall provide the total product shelf life in months or estimated lifespan in years, as applicable.
b. Products with a shelf life of less than 36 months are normally not acceptable; however, in special circumstance UNICEF may accept shorter shelf life.
c. Unless specifically authorised in writing by UNICEF prior to delivery to UNICEF, the supplier shall ensure that two thirds of the shelf life remain at delivery. Any product delivered with less than two

thirds remaining shelf life, shall be rejected by UNICEF, at no cost to UNICEF. The supplier shall be responsible for and bear the costs for returning the goods.

6. Sterile consumables/renewables

a. The supplier shall provide certificates issued by the manufacturer of all sterile devices in accordance with ISO 11135 and ISO 11137- Sterilization of health care products (as applicable).
b. Certification of the sterilization site (ISO 13485), including the standards applied for the sterilization process.
c. The supplier shall provide batch release certificates for each batch delivered to UNICEF.
d. The certificate of sterilisation shall indicate:
   - UNICEF purchase order number and item number;
   - Manufacturer's product reference and product short description;
   - Manufacturing site/sterilisation site;
   - Batch number (lot number);
   - Batch quantity;
   - Date of sterilisation;
   - Expiry date (month, year);
   - Sterilisation method;
   - Process (standard) followed for validation and routine control for sterilisation of medical devices;
   - Process (standard) followed for medical devices to be labelled "sterile"; and
   - Name of the person responsible, title, date and signature.

7. Hazardous goods

The supplier shall provide the material safety data sheets (MSDS) issued by the manufacturer, for the device or any components included in the device. In addition, the supplier shall complete relevant sections of bidding documents related to hazardous goods.

8. Product modifications

The successful bidder who is awarded a Long Term Agreement shall notify UNICEF of any product modifications (i.e. component or brand name); market clearance or any QA product certificates.

9. Sustainable production/distribution

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 encouraged to provide information on the implementation of sustainability in the production and distribution phases of the procurement cycle, with an emphasis on social and environmental responsibility.

C. Check list of attachments that shall be submitted with the offer for each product

1. Proof of conformity to Quality Management System (QMS) standards

a. **Supplier:** Valid ISO 13485 or ISO 9001 certificate (as applicable) including scope. (Copy in English.)
b. **Manufacturer**: Valid ISO 13485 certificate. (Copy in English.)

2. Proof of product conformity to production standards:

As described in the technical specifications.

3. Proof of product compliance with regulatory requirements for market clearance:

A valid certificate from one of the five founding members of the GHTF. The certificate shall indicate:

i. Name of regulatory authority
ii. Market clearance with licence number

4. Product documentation:

a. WHO Pre-qualification: If applicable and as described in the technical specifications.

b. General:
Completed Technical Questionnaire as in the tender solicitation documents.

c. Technical specifications:
Supplementary documents as requested in the tender.

i. Complete technical specifications, including technical data sheet;
ii. List of all supporting items/devices required, but not supplied;
iii. Recommended storage/transport conditions; Temperature and humidity;
iv. Waste management: Recommended safe and responsible method of waste disposal;
v. Instructions for use and training material in English, French and/or Spanish;
vi. Installation and training requirements
vii. Service and Maintenance requirements
viii. Brochure (showing the product reference)
ix. If available published field-testing studies not older than 2 years, with: Accuracy and correlation to applicable standards; and clinical effectiveness, robustness of the technology in low-income country environments where applicable
x. Estimated weight and volume
xi. Packaging photos of primary and secondary packaging with legible labelling

5. Product shelf life / life span:

The supplier shall provide the total product shelf life in months or estimated lifespan in years, as applicable.

6. Sterile consumables/renewables

For sterile products: Certification of the sterilization site (ISO 13485), including the standards applied for the sterilization process.

7. Hazardous goods:

For products classified as hazardous goods the supplier shall provide the hazardous classification and all applicable Material Safety Data Sheets for the device and/or any components included in the device. In addition, the supplier shall complete relevant sections of bidding documents related to hazardous goods.

8. Sustainable Goals: Indicate the company's efforts to implement any of the following in the coming 12 months:

a. **Environmental management:** Plans to obtain the Environmental Management System certificate, ISO 14001 or equivalent with CO_2 reduction targets. Specify which areas will be covered.
b. **Energy Management:** Plans to obtain the Energy Management System certificate, ISO 50001. Specify which areas will be covered.

c. **Standards:** Plans to conform to the Standards of Social Accountability e.g. SA8000 or ISO 26000, or other standards that demonstrate commitment to social responsibility. Specify which areas will be covered.
d. **Global initiatives:** Plans to join the Global Reporting Initiative and/or the United Nations Global Compact.
e. **Other related information:** Other plans related to sustainable production/distribution.