UNICEF TECHNICAL REQUIREMENTS FOR MEDICAL DEVICES (MD) - GENERIC

June 2022

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: ISO 13485 Quality management systems – Requirements for regulatory purposes.
Suppliers: ISO 9001 Quality management systems – Requirements for regulatory purposes.

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

2. Product compliance with regulatory requirements for market clearance

Products shall be cleared by one of the founding members of the Global Harmonization Task Force (GHTF). The products shall have a valid market license from at a minimum one the five (5) regulatory authorities listed below:

- Australia: TGA Device Licence;
- Canada: Device Licence;
- European Union: European medical device (MDD 93/42/EEC or MDR 2017/745) CE Mark;
- Japan: Device Licence;
- USA: FDA 510(k) premarket Notification Clearance or Premarket Approval (PMA), Human Device Exception Approval (HDE);

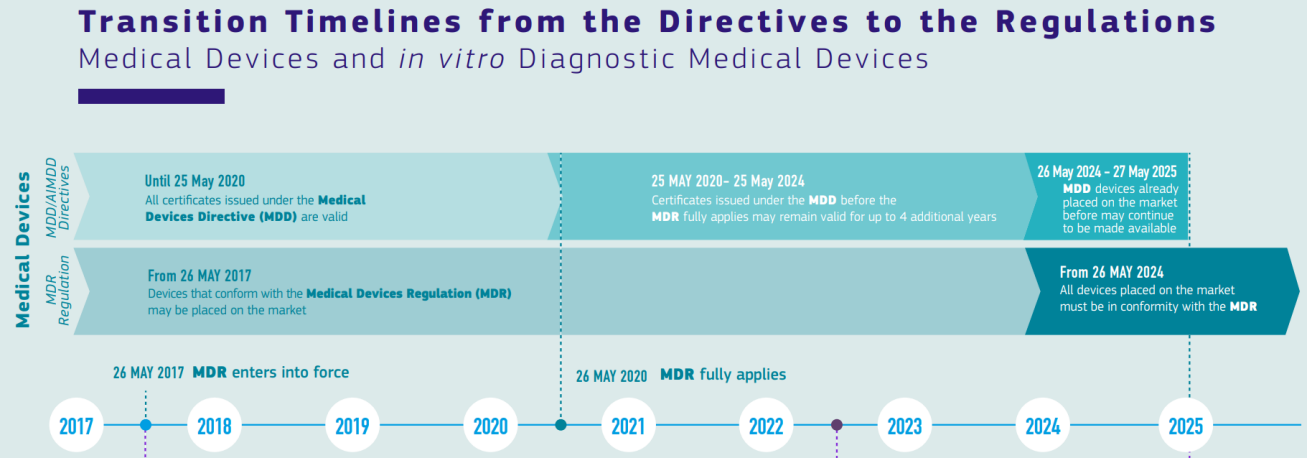
[1] *The International Medical Device Regulators Forum (IMDRF) was conceived in February 2011, to build on the strong foundational work of the Global Harmonization Task Force on Medical Devices (GHTF) and to accelerate international medical device regulatory harmonization and convergence. IMDRF: http://www.imdrf.org.*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

NOTE: Transition of EU Medical Device Directive to Medical Device Regulation

UNICEF is aware of the changes being implemented by the EU with regards to the medical device's regulatory framework. As these changes take shape and new regulations are adopted and implemented by Notified Bodies, UNICEF reserves the right to request information from current or future suppliers on how they plan to accommodate the changes so that appropriate CE certification is maintained.

Status as per June 2022

- All **Class I** medical devices should be self-declared as fully compliant with the new EU-MDR 2017/745 regulatory framework.
- All **other Classes** of medical devices are to follow below timetable regarding the transition timelines to the new EU-MDR 2017/745 regulatory framework.



https://ec.europa.eu/health/system/files/2020-07/md_infographic-timeline_en_0.pdf

3. Product conformity to harmonized international standards

a. The product(s) shall conform to applicable standards as published by International Organization for Standardization (ISO), European Committee for Standardization (CEN), and comparable organisations publishing standards, further specified in the tender documents.

b. The labelling of the product shall meet the requirements described in the regulations of at least one of the 5 regulatory authorities listed in Section B.2.

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

4. Product documentation

a. Product datasheet: Product(s) shall conform to the design, functionality and intended use stated by the manufacturer and the technical specifications stated by UNICEF. The product datasheet should include product reference, product specifications and applicable standards.

b. Marketing license: A certificate or otherwise proof that market clearance has been obtained for the specific product in-line with the regulatory requirements for market clearance under point B.2 of this document.

c. A Declaration of Conformity (DoC) clearly stating all international standards the product complies with.

Note: Where DoCs are issued in conjunction with EU CE certificates, the DOCs require to be in compliance with, either the EU MDD 93/42/EEC, or the EU MDR 7015/745 regulatory framework,. Information such as, but not limited to the authorized EU representative (applicable to manufacturers outside Europe), product code, relevant international standards, classification of the device, etc., shall be included in the DoC in compliance with the applicable directive or regulation.

d. External laboratory test reports: Where applicable, UNICEF may ask for test reports and/or certification of standards for specific products deemed high risk in the context of UNICEF's scope of activities.

e. WHO prequalification: UNICEF shall ask for the WHO pre-qualification award letter if applicable.

f. Packaging information: Conform to international standards for product packaging and labelling as indicated under point B.3.b.

g. Manufacturer's guidelines and /or instructions for use (IFU) and maintenance: For reusable products, IFU shall include cleaning instructions. IFU shall be available at least in English, French and Spanish.

IMPORTANT: 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. Where products are indicated as having a shelf life, this shelf life shall be indicated on primary, secondary and tertiary packaging.

b. Products with a shelf life of less than 5 years are normally not acceptable; however, in special circumstances UNICEF may accept shorter shelf life.

c. the supplier shall ensure that two thirds of the shelf life remain at delivery unless specifically authorised in writing by UNICEF prior to 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 (ISO13485), 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.

Note: Where products contain batteries, whether these are classified as hazardous or not, at all times a material safety datasheet shall be included in submissions. Take note that the MSDS shall be issued for batteries, where batteries are separately by-packed with equipment, and the MSDS shall be issued for equipment, where batteries are placed within equipment.

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, efforts made by manufacturers and suppliers towards sustainable initiatives are of great interest. Thus, as an asset, but not a requirement, the supplier/manufacturer 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. Attachments that shall be submitted with the offer for each product

1.	**Product documentation**	a. Completed technical form. b. Product brochures and technical datasheets. c. Product images. d. User manual in English, French and Spanish. e. Service manual (where applicable).
2.	**QMS standards**	a. The manufacturer ISO 13485. b. The supplier if the supplier is not the manufacturer, a minimum ISO 9001.
3.	**Market clearance.**	Valid certificate from one of the five funding members of the GHTF. The certificate shall indicate:
4.	**Declaration of Conformity**	Manufacturer statement on conformity of products with provided market clearances and applicable international standards.
5.	**WHO prequalification**	Where applicable proof of WHO prequalification.
6.	**For sterile products: ISO certificate on sterilization process.**	Depending on type of sterilization process: ISO 11135 or ISO 11137

7.	**Hazardous goods**	For hazardous goods and products supplied with batteries (whether installed or by-packed) a Material Safety Datasheet. Note: Even if batteries are classified as non-hazardous the MSDS should still be included in the submission.
8.	**Labelling**	Examples of product labels for primary, secondary, and tertiary packaging in accordance with stipulated regulations under the applicable market clearances for the product.

D. Sustainability considerations

Bidders are to include information on the company's efforts to implement any of the following in the coming 12 months. Where organisations are in possession of certifications related to sustainability aspects, they are encouraged to include those in the submission.

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.