UNICEF TECHNICAL REQUIREMENTS FOR MEDICAL DEVICES (MD) - GENERIC

October 2023

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[3]:**
Manufacturers: ISO 13485 Medical devices – Quality management systems – Requirements for regulatory purposes.
Suppliers: ISO 9001 Quality management systems – Requirements.

b. **For devices not classified as medical devices:**
Manufacturers and suppliers: ISO 9001 Quality management systems – Requirements.

IMPORTANT: The certificate should be issued by accredited Certification Bodies (CBs). The accreditation information of CB can be tracked through either IAF or national/regional accreditation bodies (ABs).

2. Product compliance with regulatory requirements for market clearance

Products shall have a valid market clearance by one of the founding members of the Global Harmonization Task Force (GHTF). The market clearance should be issued by one of the five (5) regulatory authorities listed below:

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[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] *Find the definition of medical devices here: GHTF SG1 - Definition of the Term Medical Device - May 2005 (imdrf.org)*

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

Transition of EU Medical Device Directive to Medical Device Regulation

The EU is implementing changes with regards to the medical device regulatory framework. As new regulations are adopted and implemented by Notified Bodies (NBs), UNICEF reserves the right to request information from suppliers on how they plan to implement changes to maintain compliance.

Status EU market clearances as per July 2023

- 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 the Regulation (EU) 2023/607 transition timelines which came into effect in 2023 March after the introduction of the EU-MDR 2017/745 regulatory framework. The medical device certificates under MDD are valid as below:

Classification	Maximum validity
Class III implantable custom-made	26 May 2026
Class III and IIb (implantable)	31 Dec 2027
Class IIb (non-implantable), IIa	31 Dec 2028
Class Im, Is, Ir	31 Dec 2028

Clarification on the MDD/MDR Transition and Extension Regulation (EU) 2023/607:

MDD certificate expires		MDD certificate extension	NOTE
a.	**Prior to: 26 May 2021**	Can no longer be extended.	Medical devices that require the Notified Body involvement under MDR, which was not required under MDD can benefit from the EU Regulation 2023/607

MDD certificate expires		MDD certificate extension	NOTE
b.	**Between: 26 May 2021 – 20 Mar 2023**	- Signed an MDR agreement with a NB prior to the expiration of the certificate or; - Granted a derogation prior to 20 March 2023 by a Competent Authority or; - Successfully completed a non-compliance related conformity assessment procedure (COP) required by Competent Authorities prior to 20 March 2023.	MDD certificate should not be withdrawn prior to its expiry.
c.	**Between: 20 Mar 2023 – 26 May 2024**	MDR Article 120 states following requirements: - The devices continue to comply with MDD; - There are no significant changes in design and intended purpose; - There is no unacceptable risk to the health or safety of patients or other relevant; - Manufacturer put in place a QMS according to MDR and submit an MDR certification application no later than 26 May 2024; - Manufacturer signs a contract with a Notified Body no later than 26 Sep 2024.	If a manufacturer intends to extend the validity of their MDD EC and maintain the product on the market, the manufacturer should provide a "Manufacturer's Declaration", according to Regulation (EU)2023/607 and Q&A.

For details and further requirements regarding the Extension of MDD/MDR, refer to:

- Q&A on practical aspects related to the implementation of Regulation (EU) 2023/607 - Extension of the MDR transitional period and removal of the "sell off" periods[4]
- Rev. 1 - Q&A on practical aspects related to the implementation of Regulation (EU) 2023/607[5]
- Flowchart to assist in deciding whether a device is covered by the extended MDR transitional period[6]

Labelling requirements

[4] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32023R0607

[5] https://health.ec.europa.eu/latest-updates/rev-1-qa-practical-aspects-related-implementation-regulation-eu-2023607-2023-07-18_en

[6] https://health.ec.europa.eu/latest-updates/flowchart-assist-deciding-whether-or-not-device-covered-extended-mdr-transitional-period-2023-08-23_en

a) 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 (above).

b) Any medical device registered for “Research Only” or “For export only” exempt, unless specifically authorised in writing by UNICEF.

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 organizations publishing standards, further specified in the tender documents.

4. Product documentation

a) Product datasheet: A summary of the product characteristics including functionality and intended use, product reference, material, size, applicable product standards, etc.

b) Marketing clearance: 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 relevant international standards with which it is compliant.

Note: Where the above DoCs is issued to support an EU market clearance, the DoC requires furthermore to be in compliance with either the EU MDD 93/42/EEC, or the EU MDR 2017/745 regulatory framework. For details see:

- Technical documentation and EU declaration of conformity - Your Europe (europa.eu)[7]

d) External laboratory test reports: Where applicable, UNICEF may ask for test reports issued by international accredited laboratories* and/or certification of standards for 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: Product packaging and labelling compliant with one of the 5 regulatory authorities listed in Section B.2. (refer 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.

h) Product images of the product and primary and secondary packaging.

***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 or estimated lifespan in months, as applicable. Where products are indicated as having a shelf life, this shelf life shall be indicated on primary, secondary and tertiary packaging.

[7] https://europa.eu/youreurope/business/product-requirements/compliance/technical-documentation-conformity/index_en.htm

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) Sterilisation certificates must be provided for all sterile devices in accordance with ISO 11135 and ISO 11137 - Sterilization of health care products (as applicable).

b) ISO 13485 Certification of the sterilization site including the standards applied for the sterilization process. (e.g. sterile packaging ISO 11607).

c) The supplier shall provide batch 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

A material safety data sheets (MSDS) issued by the manufacturer shall be provided, for the device or any components included in the device.

Note: Where products contain batteries, whether these are classified as hazardous or not, a material safety datasheet shall be included in every submission. 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

Successful bidders awarded with 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. Suppliers/manufacturers are 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

	Type of document	Remarks
1.	**Product documentation**	- Completed Technical Information Sheet - Product brochures and technical datasheets. - Product and packaging images. - User manual in English, French and Spanish. - Service manual (where applicable).
2.	**QMS standards** (Issued by either the IAF or any national/regional accreditation bodies.)	- The manufacturers ISO 13485 certificate. - The suppliers ISO 9001 certificate.
3.	**Market clearance** (Issued by authorized regulatory bodies)	Documentation of compliance with the medical device regulation from one of the five funding members of the GHTF. - Australia: TGA Device Licence - Canada: Device Licence - European Union: • EC certificate and/or • Self-declaration - Japan: Device Licence - USA: • FDA 510(k) premarket Notification Clearance or; • Premarket Approval (PMA) or; • Human Device Exception Approval (HDE) or; • For class I devices include the DI (Device Identifier)
4.	**Declaration of Conformity (DoC)**	Details on a DoC should include at a minimum: - Reference number of applicable products - Signature of manufacturer including date and location. - Applicable regulation and classification - International standards the product complies with - For sterile products: sterilization process and applicable ISO standard(s) Where the above DoC is issued to support an EU market clearance **additionally,** the following should be included: - Notified body, EC certificate, if applicable - Basic UDI (Unique Device Identifier), SRN (Single Registration Number), if applicable - Authorized EU representative, if applicable
5.	**WHO prequalification**	Where applicable, proof of WHO prequalification.

	Type of document	Remarks
6.	**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 submitted.
7.	**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

Prospective bidders and manufacturers demonstrating a commitment to integrating sustainability principles into their production processes and adhering to high social standards will be afforded precedence in the assessment of proposals.

The solicitation documentation will encompass a sustainability questionnaire that bidders are required to diligently complete and submit as part of their proposal. The resulting score from this questionnaire will factor prominently in the final evaluation of the proposal, affording bidders the opportunity to showcase their organization or products as exemplars of sustainability considerations.

Furthermore, bidders are strongly urged to furnish details regarding their company's initiatives to implement any of the following within the forthcoming 12 months. In instances where organizations possess certifications pertinent to sustainability facets, they are encouraged to incorporate these credentials in their submission, including but not confined to:

a. **Environmental management:** Plans to obtain the Environmental Management System certificate, ISO 14001 or equivalent with CO_2 reduction targets.

b. **Energy Management:** Plans to obtain the Energy Management System certificate, ISO 50001.

c. **Social accountability standards or guidelines:** Plans to conform to the Standards or Guidelines of Social Accountability e.g. SA8000 or ISO 26000, or other standards that demonstrate commitment to social responsibility.

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.