	Title:	UNDP TECHNICAL & REGULATORY REQUIREMENTS FOR MEDICAL DEVICES		
	Number:	REQ-MDP-001	Version:	V02
	Effective date:	Oct 23 2024	Pages:	19
	Review date:	Oct 22 2025		

Contents

List of Abbreviations

CAB- Conformity Assessment Bodies
DOC- Declaration of Conformity
RA – Regulatory agency
GDPMD - Good Distribution Practices for Medical Device
GHTF- Global Harmonization Task Force, currently known as International Medical Device Regulators Forum (IMDRF), a successor organization of GHTF
MD- Medical Device
NRA- National Regulatory Agency
IUD- Intrauterine device
IVD – In vitro diagnostic
EMC- Electromagnetic compatibility
MSDS Material Safety Data Sheet
LVD – Low voltage directive
QMS - Quality Management Systems
UDI- Unique Device Identifier
WHO- World Health Organization
LTA – Long term agreement

Glossary

Private Label Manufacturers (Own brand Labellers or virtual manufacturer): A private label manufacturer fully sources its own named product from another company (sometimes known as the 'original equipment manufacturer'). By placing their own name and address on the product, the private label manufacturer takes on the legal responsibilities for the medical device and is therefore regarded as the manufacturer in accordance with the medical device regulations.

Manufacturer

Any natural or legal person with responsibility for the design and/or manufacture of health products with the intention of making them available for use under the Manufacturer's name, whether or not such a Health Product is designed and/or manufactured by the Manufacturer itself or on its behalf by another person(s).

Supplier (Suppliers)

An entity that potentially or actually provides goods or other products (including intellectual property), services, and/or works to the organization. Suppliers may be agents, distributors, importers, manufacturers, traders, etc. who also may bid for UNDP tenders.

Bidder

An entity that submits an offer in response to a solicitation. Normally, the term 'bidder' is used to refer to the entity responding to an EOI, RFI, ITB, RFQ, or RFP. Once a bidder is selected and awarded the contract, they become the supplier and are responsible for fulfilling the terms of the agreement, including delivering the required goods, services, or works.

1. Background

UNDP supports countries implementing large-scale health programmes to increase access to Universal Health Coverage (UHC) within national policies and priorities. As a part of such programs, UNDP procures health products, including medicines, medical devices (MDs), personal protective equipment (PPEs), medical equipment, *in vitro* diagnostics (IVDs), laboratory equipment, and vector control products for public health. This document addresses the technical and regulatory requirements of medical devices. It is aligned with the UNDP Quality Assurance (QA) policy[1] which sets out the quality system for health products.

2. Target Audience

This document provides technical guidance to multiple entities engaged in the procurement of medical devices. The intended audience includes Bidders, Suppliers, Procurement Team, Technical Specialists Team in Country Offices, QA Team, Global Procurement Unit (GPU), and others in the procurement process. The UNDP's procurement entity must share this document with suppliers and/or bidders as a part of the solicitation process to ensure compliance with UNDP's expectations regarding the safety and quality of the medical devices.

3. Instructions to Readers

This document is written based on the International Medical Device Regulators Forum's (IMDRF) device classification and the regulatory requirements of IMDRF's founding members (Canada, USA, EU, Australia, and Japan). While the document is written to be harmonized, there may be differences in the type of regulatory assessment and the conformity elements for medical devices as these devices are classified differently from one country to another (See annex I). Bidders and manufacturers are requested to exercise caution and diligence while checking for the conformity assessment elements for each type of product class according to the regulatory requirements in the country from where marketing authorization is obtained.

UNDP retains the right to request supplementary information from bidders on an as-needed basis, as the European Commission has amended the transition period under (EU) 2023/607, dated 15 Mar 2023 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices. Regarding items offered under the extended transition timelines, the responsibility lies with the bidder and/or manufacturer to present evidence that demonstrates and documents compliance with the requirements outlined in (EU) 2023/607.

The QA Team will report any suspicion of fraud, and falsification to the relevant bodies of the UNDP. Any evidence of fraud and falsification will be treated as per the UNDP Quality policy[1].

4. Scope

[1] UNDP Quality Assurance Policy for Health Products Sep 2024

The scope includes technical and regulatory requirements that the bidders/suppliers must comply with and for the medical devices to conform to as per the UNDP's QA Policy for Health products[2]. The products covered under the scope of this document are medical devices, including imaging devices, Consumables and Disposables for medical devices, Contraception devices, Custom- made medical kits /Procedure packs, Medical furniture, Supportive equipment, & aids (intended for medical use), Protective equipment for infection control, Incontinence devices for patients, Medical equipment, its related accessories, and software, Personal lubricants, Safety box for used syringes and needles, biohazard bag, receptacle bag for body waste, non-specific consumables for diagnostic instruments etc. An exhaustive list of medical devices may be found at European Medical Device Nomenclature (EMDN) website[3].

5. General References

This document is based on the International Medical Device Regulators Forum (IMDRF) classification of medical devices (See annex I). The classification and requirements for medical devices are based on the technical documents issued by 'Global Harmonization Task Force (GHTF) Study Group 1 - Pre-market Evaluation'.

a) GHTF/SG1/N78:2012: Principles of Conformity Assessment for Medical Devices
b) IMDRF/GRRP WG/N47 FINAL:2018 Essential Principles of Safety and Performance of Medical Devices and IVD Medical Devices
c) IMDRF/IVD WG/N64 FINAL:2021 (formerly GHTF/SG1/N045:2008) GHTF SG1 Principles of Medical Devices Classification - November 2012
d) IMDRF/GRRP WG/N52 FINAL, Principles of Labelling for Medical Devices and IVD Medical Devices: 2019
e) GHTF/SG1/N065:2010: Registration of Manufacturers and Listing of Medical Devices
f) IMDRF/SaMD WG/N12FINAL:2014 Software as a Medical Device: Possible Framework for Risk Categorization and Corresponding Considerations
g) IMDRF/SaMD WG/N23FINAL:2015 Software as a Medical Device (SaMD): Application of Quality Management System

6. Technical & regulatory requirements for medical devices

6.1 Requirements for products for market clearance

Annex II shows a typical list of conformity elements for MDs that UNDP would need based on the risk classification of the item under offer. This applies to spares and consumables including software which are classified as MD.

6.1.1 Class A, B, C, and D medical devices

Medical devices offered to UNDP must comply with one or more of the regulatory requirements based on the IMDRF risk classification.

6.1.1.1 Class A medical devices (non-sterile, non-measuring, non-reusable)

At a minimum, medical devices that fall under Class A (non-sterile, non-measuring, non-reusable) must have regulatory approval in or declared to the NRA of the country of manufacture. UNDP will also

[2] UNDP Quality Assurance Policy for Health Products Sep 2024

[3] European Medical Device Nomenclature (EMDN) (europa.eu)

accept class A device if they meet or one or more of the criteria mentioned in section 6.1.1.2. The product shall meet the requirements of Essential Principles of Safety and Performance of Medical Devices as described by IMDRF[4].

Some of the examples of devices falling under this class includes bandages, dressings for non-invasive applications, devices for body orifices for invasive applications for transient use such as examination gloves, enema devices etc[5].

All class A Self-certified devices conforming to European regulations must confirm to EU MDR 2017/745.

6.1.1.2 Class A (sterile, measuring), B, C and D devices

The medical devices must meet one or more of the criteria from the below list from a to d.

a) Market clearance from at least one of the regulatory agencies mentioned below:
- Australia: Therapeutic Goods Administration (TGA) Device Licence for both IVDs and Medical devices
- Canada: Device Licence, Medical Devices Regulations (SOR/98-282) for both IVDs and medical devices
- European Union: Evidence of compliance with either MDD 93/42/EEC or MDR (EU) 2017/745, as applicable and per European Commission transition dates, CE Mark for medical devices. These will apply in line with the enforcement dates published by European Commission. Regarding items offered under the extended transition timelines under (EU) 2023/607, the responsibility lies with the bidder and/or manufacturer to present evidence that demonstrates and documents compliance with the requirements outlined in (EU) 2023/607.
- Japan: Device Licence from Pharmaceuticals and Medical Devices Agency (PMDA)
- USA: FDA 510(k) premarket Notification Clearance or Premarket Approval (PMA), Human Device Exception Approval (HDE). For Class I 510(k) exempt medical devices, the medical device manufacturers shall be registered with FDA and medical devices shall be listed with FDA. Proof the same shall be provided.

b) The medical devices that are eligible to offer as 'WHO PQ' must be prequalified as per WHO PQS program. The list of prequalified devices is available online Prequalified Devices and Equipment. UNDP recognizes the WHO prequalified MDs for procurement purposes, relying on the declaration of equivalence as outlined in Annex III.

c) Authorized for use by the WLA for the relevant product stream[6] and all relevant regulatory functions.

d) Recommended for use by the ERP for medical devices.

6.1.1.3 Condoms, intra-uterine devices (IUDs)

In addition to the criteria mentioned in 6.1.1.2, UNDP recognize the UNFPA prequalification program. UNDP recognizes the UNFPA prequalified condoms/IUDs for procurement purposes, relying on the declaration of equivalence as outlined in Annex III.

6.1.1.4 Personal lubricants

In addition to the criteria mentioned in 6.1.1.2, UNDP recognize the UNFPA prequalification program. UNDP recognizes the UNFPA prequalification for the personal lubricants for procurement purposes,

[4] Essential Principles of Safety and Performance of Medical Devices and IVD Medical Devices (imdrf.org)
[5] GHTF SG1 Principles of Medical Devices Classification - November 2012 (imdrf.org)
[6] List of WHO Listed Authorities WLAs https://www.who.int/initiatives/who-listed-authority-reg-authorities

relying on the declaration of equivalence as outlined in Annex III. The offered product must meet the WHO/UNFPA specifications for personal lubricants.

6.2 Requirements for manufacturing sites

6.2.1 Quality Management System (QMS) standards:

Bidders, suppliers, manufacturers, and private label manufacturers (also known as own-brand labellers or virtual manufacturers) shall conform to the following quality management system standards (as per the current revision), as applicable. The scope of the certificate shall cover the product type, services, activity offered (e.g., design, development, and distribution of medical software for cardiac and patient monitoring; design and development, production and distribution of ventilators and respiratory apparatus etc).

a. For products classified as medical devices A (sterile, measuring), B, C and D: Manufacturers shall comply with:
   i. the ISO 13485 QMS or
   ii. US FDA 21 CFR 820 QSR or
   iii. the GHTF founding country's version of the ISO 13485 standard or
   iv. Medical Device Single Audit Program (MDSAP) audit conducted by a recognized auditing organization by the GHTF founding countries.

The QMS certificate should be issued from a Conformity Assessment Body (CAB) that is

   i. authorized/registered/licensed by an NRA in one of the GHTF founding members or
   ii. authorized/registered/licensed by an NRA in one of the WLA for the relevant product stream and all the relevant regulatory functions; or
   iii. Conformity to standards will be established by a CAB that is accredited to carry out conformity assessment according to international, national, or regional standards by an accreditation agency appointed by national regulatory/competent authority of one of the GHTF founding members.

b. For products classified as medical devices Class A (non-sterile, non-measuring): As an alternative to 6.2.1 (a), the conformity to QMS standards is acceptable if the CAB issuing the QMS is

   i. to carry out conformity assessment according to international, national, or regional standards by an accreditation body recognized by the International Accreditation Forum (IAF)[7] or
   ii. an accreditation authority that is authorized by a national regulatory/competent authority of one of the IMDRF members
   iii. Any of the CABs mentioned in Section 6.2.1a

c. If a part or full manufacturing activity is subcontracted by the legal manufacturer (for example, manufacturing, sterilization, kitting, etc.), then the requirement for an independent QMS also applies to the critical subcontractor(s).

d. Where the manufacturer chooses a type examination and product conformity verification as an alternative means of demonstrating conformity with the relevant Essential Principles of Safety and Performance (IMDRF/GRRP WG/N47), a QMS for the manufacturing activities shall be submitted. In such cases, UNDP reserves the right to make the final decision.

[7] https://iaf.nu/en/recognised-abs/

e. If the item offered to UNDP is WHO-prequalified, bidders shall submit a declaration of equivalence for each product including the components regarding its prequalification status as per the template provided in Annex III. UNDP reserves the right to ask for additional documents according to defined procedures. The bidder will supply the product as declared in Annex III- Declaration of equivalence for Medical Devices or Other Devices Submitted Based on WHO Prequalification

7. Requirements for Bidders

Bidders that are not manufacturers are expected to comply with all the requirements of ISO 13485. While ISO 13485 certificates are preferred, UNDP may accept ISO 9001 certificates. In the latter case, the bidders should also submit a written, signed, and dated statement of compliance with ISO 13485 QMS. Good Distribution Practices for Medical Devices (GDPMD) or equivalent should also be in place for all bidders dealing with medical devices.

The bidder must ensure that that the supply chain, encompassing storage and transportation, complies with the product manufacturer's specifications, including factors such as temperature, humidity, or any other relevant requirements.

8. Product Documentation

Bidders including the current LTA suppliers of the UNDP shall provide high-level technical documentation that demonstrates conformity to the Essential Principles of Safety and Performance for items under offer, as per the Essential Principles of Safety and Performance of Medical Devices and IVD medical devices (IMDRF/GRRP WG/N47). Such technical documents include the following:

8.1 Device Description

Such description includes: Product name, unique product identifier, and a general description of the device, including its Intended use / Intended purpose; the intended patient population and indications of use; the principles of operation of the device; the class of the device and the applicable classification rule according to the regulations applied; a description of the accessories, other medical devices and other products that are intended to be used in combination with the device; a description or complete list of the various configurations/variants of the device, etc. Bidder shall provide all relevant information as applicable to the item under offer.

8.2 Packaging and Labelling

The packaging and labelling of the product shall meet the requirements described in the regulations of at least one of the five regulatory authorities as mentioned in section 6.1. Besides, one can refer to the labelling requirements described in the Global Harmonization Task Force document IMDRF/GRRP WG/N52 FINAL.

The medical device and the primary package shall have labels with information such as product name/brand/trade name, net quantity of contents, manufacturer’s name and address, unique device identification (UDI), special handling measures or permissible environmental conditions for storage and transport, authorized representative as applicable, product REF/catalogue number, name of the importer if applicable, lot (batch) number, expiry date, symbols as applicable, information on sterile state if supplied sterile, warnings or precautions, indications for use, contraindications, disposal instructions etc. This is applicable to the components of the medical device kits, as applicable.

Labelling, **instruction for use or user manual** must be provided in the following languages: English, Spanish or French, or as per request based on the recipient country.

Photographs of labels, primary, secondary, and tertiary packaging for the item(s) under the offer shall be provided by the bidders. In the case of medical and/or electrical equipment, a picture of the equipment ID plate shall be provided.

If the photographs of the labels cannot be provided at the time of offer, UNDP will consider signed and approved packaging and labelling artwork issued by the manufacturer's QA. If artwork is presented during the RFQ stage, the bidder shall submit a picture of the primary package labelling including the ID plate, at the purchase order stage, which will be reviewed by the UNDP QA Team.

8.3 Product specification

Details such as size, dimension, weight of the item, features, and performance attributes of the medical devices, substantiated claims of the devices, and their variants and accessories, as applicable, shall be provided.

Recommended temperature and humidity for transport and storage shall be provided.

For all electrical items, the bidder shall provide the specified voltage and plug type as detailed in the technical specification shared by UNDP. Alternatively, the bidder may list of available voltage and plug types for the item and if contracted, the correct voltage and plug type should be supplied for the respective country of destination.

8.4 Software as MD (SaMD)

All software that meets the definition of a medical device must conform to the essential principles to assure the product's safety, quality, and performance.

- Market clearance and quality Management System (QMS) as per section 6.1 and 6.2 respectively.
- The manufacturer should comply with the ISO/IEC 62304 standard – medical device software – Software life-cycle processes and IEC 62366:2007 Medical devices — Application of usability engineering to medical devices.
- Minimum labelling requirements apply to medical device software, regardless of whether it is downloaded from the Internet, installed from a CD, or pre-installed by the manufacturer on a device.
- Data protection: In the case of personal data handling by the software, the bidder shall demonstrate compliance with the regulation in the country of use and with the regulation of one of the GHTF founding members.

UNDP reserves the right to ask for additional documents to assess compliance with regulations.

8.5 Research Use Only Products

The UNDP will conduct a thorough review of any medical device labelled as "Research Use Only (RUO)", and additional documentation may be requested for evaluation. Bidders must refrain from offering RUO products unless specifically requested by the UNDP requesting entity. In cases where there is no regulated device in the market, the bidder should explicitly state that in the offer.

8.6 Certificate of Sterilization

Certificate of sterilization: For MDs that are supplied sterile, the bidder shall provide certification of the sterilization site (ISO 13485), including the standards applied for the sterilization process, such as

- ISO 11135 (ETO sterilization)
- ISO 11137 (Gamma Irradiation)

- ISO 17665 (Steam sterilization)
- ISO 20857 (Dry heat)
- ISO 14937 (for any other sterilization method).

The relevant certificate shall also be submitted at the bidding stage.

Batch release certificates: The bidder shall arrange batch release certificates for each batch delivered to UNDP at the time of shipment and shall be included in the shipping documents. The individual batch sterilization certificate for each batch shall have all relevant information such as UNDP purchase order number with item code or stock code, product name, manufacturing site, sterilization site, batch number, the applicable standard applied, etc. The certificate should be approved by the authorised personnel.

8.7 Product shelf life

The bidder shall provide shelf life in months (as applicable) based on the manufacturer's stability or sterility shelf-life studies. Any exceptions to the total shelf-life requirements at the PO stage/bidding stage shall be brought to the attention of the UNDP QA Team/UNDP GPU country focal point for exceptional approval.

Regarding the remaining shelf-life requirements at the time of dispatch of goods from supplier's premises, the supplier must ensure a minimum remaining shelf-life of 75% to 85%[8]. Any discrepancies regarding the above-mentioned remaining shelf life must be promptly communicated to the UNDP GPU country focal point.

8.8 Conformity to harmonized international standards

The product(s) shall conform to applicable standards as per International Organization for Standardization (ISO), or equivalent standards published by similar organizations recognised by the founding members of the GHTF/IMDRF.

For all software which are classified as MD, the product shall show conformity to ISO/IEC 62304 standard – medical device software – Software life-cycle processes.

8.9 Declaration of Conformity

The bidder shall arrange the Declaration of Conformity (DoC) to the defined applicable regulation(s) and/or standard(s) applied mentioned in section 6.1. This DoC shall be established according to the model stated in ISO/IEC 17050 or as per applicable regulations. The DoC submitted in requirement with the EU MDD 93/42/EEC or EU MDR 2017/745 regulatory framework shall have details such as a statement from the manufacturer, classification & conformity route, applicable standards, conformity to other directives as applicable, date & signature by the manufacturer, device identifier, list of accessories or components, details of EU authorised representative for manufacturers outside Europe etc.

8.10 Third party laboratory test reports

Where applicable, UNDP may ask for test reports and/or certifications for specific products deemed high risk items for procurement. Such reports and/or certifications must be issued by laboratories accredited as per ISO/IEC 17025: General requirements for the competence of testing and calibration laboratories.

[8] [7] TRS 1044 - Annex 8: Points to consider for setting the remaining shelf-life of medical products upon delivery (who.int)

8.11 Hazardous goods

For devices that contain materials classified as “hazardous goods” or any kind of batteries, the bidder shall provide the manufacturer's material safety data sheets (MSDS). MSDS for batteries shall be issued if batteries are packed separately, while in the cases where devices contain batteries, the MSDS shall be issued for equipment/device.

9. Product Changes

After awarding the long-term agreement or issuance of a purchase order (PO) for specific products, if there are any changes or modifications made to the device, the LTA/PO awardee shall notify UNDP QA, and UNDP QA reserves the right to reconsider the approval based on the supporting documents provided.

10. Vigilance and quality issue

During the period of the long-term agreement, the LTA/PO awardee shall notify UNDP QA, without undue delay, of any alert or quality issue related to the qualified product. Any adverse event (complaint, internal nonconformity alert, or quality issue related to the qualified product) leading to one of the following outcomes:

- Death of a Patient, User or Other Person
- Serious Injury of a Patient, User or Other Person
- No Death or Serious Injury Occurred but the Event Might Lead to Death or Serious Injury of a Patient, User or Other Person if the Event Recurs

must be investigated and corrective actions such as field safety notice and/or product recall must be defined and implemented, if necessary, in compliance with regulation.

11. Certificates

Suppliers and manufacturers must submit valid and current copies of certificates of compliance to technical and regulatory requirements mentioned in Annex IV. It is the supplier’s responsibility to check the expiry of the certificates before submitting to UNDP.

12. Registration of manufacturers and their devices

Bidders shall furnish UNDP with a copy of the valid registration certificates for the manufacturing facility and the device (e.g., manufacturing license) issued by the regulatory agency.

13. Other requirements

13.1 Warranty

A copy of the terms, conditions, duration of warranty shall be provided at the time of the offer. Terms can include the warranty against defects and the bidder or manufacturer can refer to quality, state, condition, performance, availability of parts and service. Warranty shall be extended as per client's agreement.

13.2 Installation

If applicable, the bidder must guarantee the Installation of the device. Installation refers to the process of securely placing or fixing the device at the desired location specified by the UNDP client.

13.3 Commissioning and Training

If applicable, the bidder must guarantee the commissioning of the device, that consists of a series of tests and adjustments performed to verify the proper functioning and safety of the equipment before it is put to operation. Additionally, training in the use of technology will normally be included with commissioning.

13.4 After Sales Maintenance Services

This refers to the main procedures for inspection for performance and safety, as well as preventive and corrective maintenance which ensures that the equipment is operating correctly, and the equipment is safe for both patients and operators. Agreements can be established with bidders or manufacturers as per request. When applicable, comprehensive information regarding service, repair, and spare parts must be provided at the time of offer. Additionally, adequate training on maintenance, including both preventive and corrective measures, should be offered.

The bidders shall ensure that spares and consumable for a dedicated medical device shall be available during the entire lifetime/life span of the equipment/device.

13.5 Decommissioning of the device

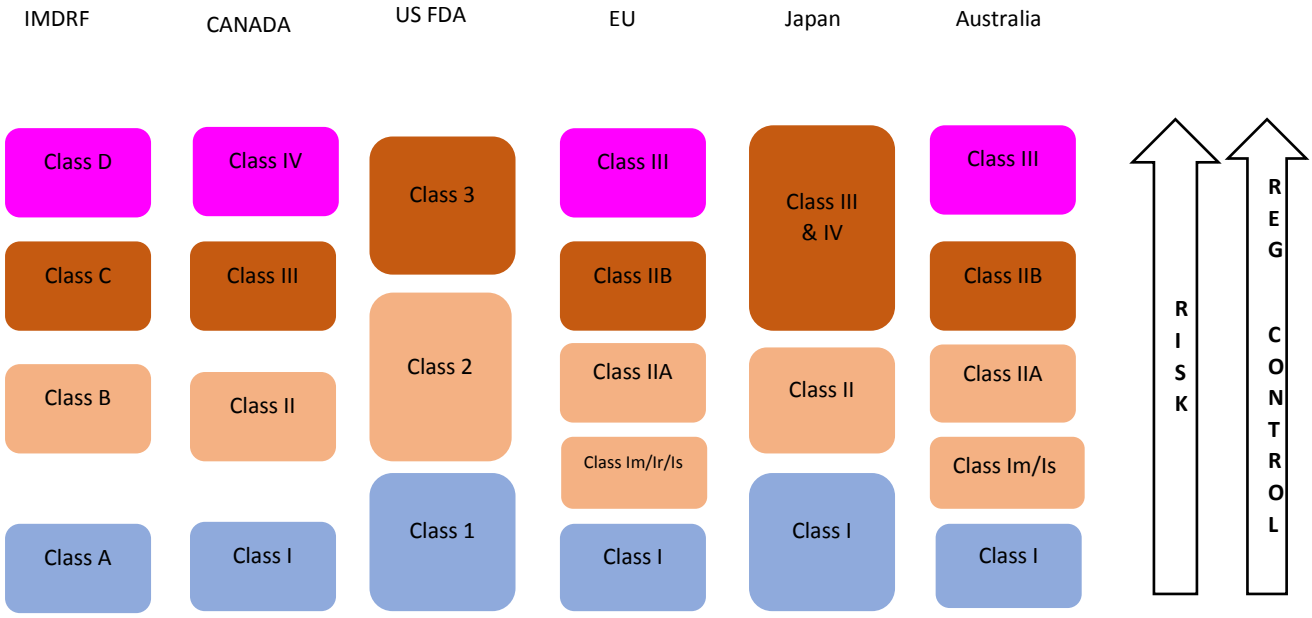
Where appropriate, the necessary information, as per local regulations, shall be provided for the safe disposal or decommissioning of the device after its recommended time of use.

14. Documents to be submitted

Proof of all the technical and regulatory requirements shall be accompanied by copies of the current and valid certificates at the time of offer. All submissions must be in English or in a language as stated in the bidding documents. See Annex IV for the check list for document submission. Bidder shall provide clarifications in the event of non-availability of proof/certificates that are mandatory at the time of submission. Depending on the foreseeable use of a product, the QA team may request additional documents, as applicable.

Annex I: Pictorial representation of medical device classification in GHTF founding member countries.

Medical devices showing the risk and regulatory control:



Annex II- List of conformity assessment elements for MDs for Manufacturer and product (Guidance for Bidders and Manufacturers)

Conformity Assessment Elements	**Class A (Self-declared)**	**Class A (sterile, measuring)**	**Class B**	**Class C**	**Class D**
QMS for manufacturer	As a minimum, ISO 13485 certificate or equivalent issued by a CAB recognized by IAF, or by an accreditation authority authorized by a national regulatory/competent authority of an IMDRF member, or by an NRA in one of the GHTF or WLA member countries.	ISO 13485 certificate or equivalent issued by a CAB as per requirements stated in Section 6.2.1a. Full QMS or QMS excluding design and development controls	ISO 13485 certificate or equivalent issued by a CAB as per requirements stated in Section 6.2.1a. Full QMS or QMS excluding design and development controls	ISO 13485 certificate or equivalent issued by a CAB as per requirements stated in Section 6.2.1a. Full QMS	ISO 13485 certificate or equivalent issued by a CAB as per requirements stated in Section 6.2.1a. Full QMS
Technical documentation	Yes	Yes	Yes	Yes	Yes
Declaration of conformity (DOC) as per ISO 17050	Yes	Yes	Yes	Yes	Yes
Copy of the valid manufacturing license (Products must have regulatory approval in or declared to the NRA of the country of manufacture.)	Mandatory	Yes (copy on request by QA)	Yes (copy on request by QA)	Yes (copy on request by QA)	Yes (copy on request by QA)
Certificate of marketing authorization or approval by one of the GHTF founding members or WHO PQ'ed with declaration of equivalence as per Annexe III or Authorized for use by the WLA or recommended by ERP (Refer section 6.1)	Not mandatory	Yes	Yes	Yes	Yes
Regulatory approval in or declared to the NRA of the country of manufacture	Yes	Yes	Yes	yes	Yes
Proof of labelling in English as per regulations applied as per specific GHTF founding country's RA or in line with any GHTF founding member RA for Class A devices (Pictures of product, labels, ID plate, primary and secondary packaging etc)	Yes (as per regulations applicable in the country of manufacture)	Yes	Yes	Yes	Yes
MSDS	For hazardous goods or items supplied with battery	For hazardous goods or items supplied with battery	For hazardous goods or items supplied with battery	For hazardous goods or items supplied with battery	For hazardous goods or items supplied with battery

Annex III: Declaration of equivalence for Medical Devices or Other Devices Submitted Based on WHO Prequalification/UNFPA Prequalification (Ver 02)

TO BE COMPLETED BY THE BIDDER IF ITEM IS OFFERED AS WHO/UNFPA PQ'ED

Name of the Applicant (Manufacturer)		
Tick as applicable	Bidder	Manufacturer
Product Name and product REF as it appears on the label		
Product category (Immunization Devices, IUD, Condoms, Personal lubricant, Waste management products etc)		
WHO PQS code and report		
UNFPA prequalification code and report		
Date of submission		

I, {Full name}, {Job title} at {Company's full legal name}, hereby confirm the following for WHO PQ'ed/UNFPA prequalified Health products:

- The information and documentation supporting this dossier submission are true and correct per the latest edition of the_____(WHO PQS catalogue of **Prequalified Devices and Equipment/UNFPA prequalification, select as applicable).**
- The product name, the product code (REF), the regulatory version, manufacturing site will be the same as listed in the product dossier assessed and inspected by _____(WHO/UNFPA, select as applicable).
- The product's intended use is the same as detailed in the_____ (WHO report/UNFPA report, select as applicable).
- The primary packaging and labelling information will be the same as listed in the product dossier assessed and inspected by _____ (WHO /UNFPA, select as applicable).
- There are no deviations in the product submitted from the_____ (WHO-prequalified product/UNFPA prequalified product, select as applicable)other than those shared in Table 1.

Table 1: The only differences are (*please insert differences in the table following the example*):

Difference[9]	PQ'ed Product	Product supplied to UNDP
Example: Labelling	*Spanish language*	*English language*

[9] Explanation of differences:
Minor differences which may be listed here include: (i) change of language, additional languages (ii) different secondary packaging size and type.

I declare that the product submitted by {**Insert full company legal name here**} is the same as the ones prequalified by _____ (WHO PQS catalogue of **Prequalified Devices and Equipment/UNFPA prequalification, select as applicable)** except for the minor deviations listed in Table 1.

Product Details:
Product name and REF (as per labelling): _____

List of accessories/components pre-qualified along with main equipment/device (Include a table if there are many items):_____

WHO PQS report/UNFPA report to be attached with the offer: _____

Prequalification and market authorization details:
Product is prequalified from (WHO PQS)[10] that holds a valid WHO PQ report number and/or market clearance by one of the Regulatory Authorities of the Founding Members of GHTF when stringently assessed (Australia, Canada, European Union, Japan, and USA FDA). List all the market clearance as applicable.

WHO PQ Reference number: _____

UNFPA PQ reference number: _____

Marketing authorization country: _____

Marketing authorization number or certificate, if applicable: _____

Additional information for the Product supplied to UNDP if any: _____

Seal and Signature: _____

Name of authorized signatory:_____

Place: _____ Date: _____

[10]Whenever a new product is pre-qualified, a data sheet is published on the PQS website. This document and the individual product data sheets are available on the internet only at:
http://apps.who.int/immunization_standards/vaccine_quality/pqs_catalogue/index.aspx

Annex IV– Document Submission Checklist for Bidders, encompassing spares and consumables in the category of MD (X denotes 'required by UNDP')

No.	Required Document	Details	MD	WHO PQed /UNFPA PQ'ed
Documents required for evaluation				
Technical documentation				
1	Technical data Sheet	• Product details: item description, model name, manufacturer's product reference, brand/trademark, Brochure etc • Manufacturer details: manufacturer's name and address, OEM name and address, as applicable • Technical specification: Intended use, technical specifications including shelf life, voltage, plug type for electrical items), and the list of applied standards. • Spares and consumables: Details of mandatory spares and consumables • For RUO offers, declaration from supplier stating that the absence of regulated version and that the offer is as per UNDP CO request.	X	X
2	Instruction Manual or Instructions for Use	Instructions for use, transport, storage, disposal, along with temperature and humidity recommendations for transport and storage, as well as the operation manual, if applicable.	X	X
~~3~~	Labelling (Product and packaging)	• Photos of the product and labelling with all information visible (product name, UDI, packaging information for primary, secondary, tertiary packaging, etc • Equipment label for all equipment	X	X
~~4~~	Evidence of compliance to standards	For Class A (non sterile, non-measuring) devices, test Report issued by an accredited QC Laboratory in accordance with ISO 17025.	X	N/A
5	Declaration of equivalence	Annex III, as applicable	NA	X
Regulatory documents *(Copies of current and valid certificates must be submitted)*				
6	Quality Management System Certificate	• QMS for legal manufacturer(s) • QMS for private labellers, and critical subcontractors, as applicable	X	N/A
7	Marketing Authorization	• Market clearance certificate as per applicable sections of 6.1, based on risk classification A, B, C, or D (EC Certificate, Medical Device License, Inclusion on the ARTG, US FDA Clearance or Approval, etc) • For items offered under EU regulation 2023/607, supplier to submit (1) A self-declaration from manufacturers to continue to place devices on the EU market after expiration of the MDD CE certificate under 2023/607 regulation (2) A confirmation letter from notified body confirming extension of EC Certificate valid under MDD/AIMDD	X	N/A
8	Declaration of conformity	• DoC as per ISO 17050, drawn up according to <u>all</u> applicable legislation (medical devices, electrical equipment, pressure equipment, etc.). listing all applied international standards	X	N/A

No.	Required Document	Details	MD	WHO PQed /UNFPA PQ'ed

		• For all devices classified as Software as medical device, proof of compliance to standards
		  • IEC/ EN 62304 Medical device software -Software life-cycle processes
		  • IEC/EN 62366-1 Medical devices - Application of usability engineering to medical devices		

9	Manufacturing authorization	Manufacturing Authorization or Manufacturing license issued by the competent authorities (as per QA Policy requirements)	X	N/A
10	Certificate of compliance with additional applicable regulations	Other applicable EU directives or equivalent for medical electrical equipment, compressed gas equipment, oxygen cylinder, autoclave etc. (EMC/LVD/REACH/RoHS/PED/TPED/machinery directive etc)	X	N/A
Documents to be submitted with shipment or on request				
11	Certificate of analysis	As applicable	X	X
12	Batch release certificate	For sterile products, high-quality requirement devices (i.e. implantable devices)	X	X
13	Certificate of conformity	As applicable	X	X
14	Certificate of calibration	As applicable, with Maintenance and Calibration Plan	X	X
15	Sterilization Certificate	As applicable	X	X
16	Third party test reports	As applicable	X	X
17	MSDS (Material Safety Data Sheet)	As applicable (for chemicals, reagents, batteries and other dangerous goods)	X	X
18	Factory Inspection certificate	As applicable	X	X
Requirements for Non-LTA Bidders				
19	For offers made by NON-LTA bidders	Name and address	X	X
		Quality management system certificate and Good Distribution and Storage practice certificate or equivalent	X	X
		A verification report signed by the bidder's authorized personnel and supporting documentation that established the compliance of the product submitted for the bidding and supplied to the user	X	X
		Copy of the agreement with the manufacturer showing as an authorized bidder to the manufacturer or declaration from the manufacturer that the bidder is authorized for provisions, as applicable	X	X

**Proof or copy shall be provided for each of the requirements either separately or as a part of the technical documents. Copies of all documents shall be current and valid at the time of submission.*

	Name	Position	Date and Signature
Author	Elizabeth K Abraham	Quality Specialist, Health Products	Oct 23 2024 DocuSigned by: Elizabeth Abraham D2BAA9C14C614AC...
Approver	Seloi Mogatle	QA Advisor, Health Products	Oct 22 2024 DocuSigned by: Seloi Mogatle 11FAEA2A93054F2...

HISTORY OF CHANGES

Version No	Revision No	Date	Description of changes
01	00	24-01-2024	Initial release
02	00	23-10-2024	Implementation of QA policy Sep 2024 • Simplifying the requirements for QMS and market authorization for Class A (non-sterile, non-measuring) devices. • Recognition of market authorisation by WLA • Recognition of product approvals by other UN agencies and ERP • Minor language corrections • Minor changes in Annex III and IV