

Annex 5

UNFPA Technical Requirements for MEDICAL DEVICES

1. Introduction

The following document provides UNFPA's technical requirements in the procurement of medical devices (medical equipment, renewable medical supplies and medical kits excluding pharmaceuticals that might accompany kits). It is intended to give to submitters all the necessary information for them to complete understandable and homogenous dossiers.

From a general standpoint, UNFPA's technical requirements are based on the current standards and regulations, for both manufacturer's quality assurance and devices compliance.

The technical requirements also apply when the submitter is not the legal manufacturer ¹(i.e.: a distribution company). In this case, a letter from the manufacturer authorising the supplier will be required.

ELIGIBILITY: Only medical devices / equipment that have a CE mark and/or FDA 510k clearance, and that are actually marketed in Europe and/ or US are eligible for bidding.

2. General references

2.1. International guidance

UNFPA recognizes recommendations by the International Medical Device Regulators Forum (IMDRF). The following guidance shall be taken into consideration by the manufacturer:

- *GHTF/SG1/N68:2012: Essential Principles of Safety and Performance of Medical Devices*
- *GHTF/SG1/N77:2012: Principles of Medical Devices Classification*

GHTF/SG1/N78:2012: Principles of Conformity Assessment for Medical Devices. For more information on IMDRF, refer to the IMDRF website: <http://www.imdrf.org/>.

2.2. Declaration of conformity

The submitter shall provide a declaration of conformity to applicable regulation(s) and/or standard(s). This declaration of conformity shall be established according to the model given in **ISO/IEC 17050**. Declaration of conformity shall be dated and signed by the manufacturer, it contains a reference to the medical device (name and product code) and a list of relevant ISO standards and

¹"Manufacturer" means any natural or legal person with responsibility for design and/or manufacture of a medical device with the intention of making the medical device available for use, under his name; whether or not such a medical device is designed and/or manufactured by that person himself or on his behalf by another person(s) – *GHTF-SG1-n055-definition of terms*

directives for which the compliance is declared to. Declaration of conformity is a legally binding document.

Manufacturer shall provide evidence that the product has been sold to Europe or the U.S. Additional evidence of market clearance in other large economic jurisdictions with strong regulatory systems, i.e. the IMDRF representative countries will be an added advantage.

For CE marked products, the manufacturer shall provide EC Representative (EC Rep) contact details and Country.

2.3. Compliance with regulatory requirements

Medical devices proposed to UNFPA for procurement and supply must be from manufacturers who are legally registered to manufacture the particular device by their national regulatory authority and have valid manufacturing licences.

Any official clearance or legal certificates, (e.g. 510 k/PMA clearance, CE certificates conforming to EU Council Directive 93/42/EEC (MDD) or EU Regulations 2017/745 (MDR), or equivalent licences shall be provided, where applicable).

Compliance to EU Council Directive 93/42/EEC (MDD) or EU Regulations 2017/745 (MDR) with valid EC Certificate and Declaration of Conformity for the CE mark is applicable.

Note : For manufacturers which are supplying CE certificates under the MDD, a legalized declaration letter from the manufacturer that it is working towards compliance to MDR is required. Additionally, the manufacturer shall submit objective evidence to demonstrate compliance to MDR within 1 year after supply awards have been given and signed.

UNFPA reserves the right to change the probationary period of one year to an appropriate length of time which could be shorter than one year."

Updates from other recognized regulatory requirements as relevant.

Manufacturer shall provide evidence of clinical studies to all but class I non-sterile, non-measuring medical devices e.g a copy of the study results.

Manufacturer shall provide relevant Post Market Surveillance evidence and reports appropriate for the device class in accordance with EU Council Directive 93/42/EEC (MDD) or EU Regulations 2017/745 (MDR).

If available, third party laboratory test reports (declaring the name of laboratory and accreditation status) shall be submitted as part of the medical device dossier.

2.4. Quality Management System standards

The manufacturer of the product shall provide evidence that their quality management systems conform to the current version, at the time of the submission to the following quality management system international standards (or local – national transcription of these standard)

- ⇒ ISO 9001 – Quality Management Systems: Requirements
- ⇒ ISO 13485 – Medical Devices: Quality Management Systems

Manufacturer shall provide a post-market study report covering the last 3 years.

Manufacturer shall provide a copy of the latest audit report by an European health product distributor, if available.

2.5. Quality Management System of a subcontractor

In the case where a significant part of the production processes is subcontracted by the legal manufacturer to a contractor (for example, the final sterilization, final assembly, sub part manufacturing, etc.), then the requirement for an independent QMS also applies to the contract manufacturer(s).

3. Conformity of products with specific safety / performance standards

3.1. List of applicable standards

The standards to which the device is claimed to be compliant to should be part of a list of the current version of local recognized standards (e.g. EC list of harmonized standards, as published on the OJCE, FDA recognized standards, etc.). Proof of conformity to product specific standards shall be provided for the product category covering the products (and product codes) to be supplied.

To enable undisputable product identification for medical devices, it is essential to indicate an accurate Manufacturer's Product Code (product reference number, article code). If a medical device distributor acts as the legal manufacturer, there may be a product code given by the distributor that is different from the one provided by the manufacturer. Distributor is to declare both codes to the UNFPA.

3.2. Sterile products:

3.2.1. Certification of the sterilization process

The sterilization plant (the manufacturer itself or any contract sterilizer company) that performs this task shall be covered by a valid ISO 13485 certificate for the specific sterilization process:

- ⇒ 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 bid stage.



3.2.2. Individual sterilization batch certificates

During bid evaluation, UNFPA requires copies of certificates of sterilization from the last 3 most recently released batches from the manufacturer.

Note: The individual batch sterilization certificate must be issued by the legal manufacturer, who owns the entire responsibility of the compliance of the finished device.

During the procurement phase, certificates of sterilization for each batch procured by UNFPA shall be provided to the pre-shipment inspector for each Purchase Order.

3.2.3 Storage and Transportation conditions

Majority of sterile medical devices are time and temperature sensitive.

Manufacturers shall comply with the UNFPA guidelines for storage and transportation of sterile products. This implies that data loggers shall be included in shipments containing [sterile medical devices](#).

3.3. Packaging and labelling

Primary packaging shall be by unit of use and secondary packaging shall provide protection of the packaged individual units in a box.

Photos of primary and secondary packaging shall be provided accurately representing the product UNFPA will receive.

Photos of primary and secondary labelling shall be provided accurately representing the product UNFPA will receive.

Labelling shall meet, at least, the requirements described in the Global Harmonization Task Force document: GHTF/SG1/N70:2011: Label and instruction for Use for Medical Devices. The language should be in English or Spanish or French as specified.

Symbols used with medical device labels , labelling and information to be supplied (e.g. Information For Use leaflet) shall comply with the current version of ISO 15223 Part 1.

Labelling on the medical device itself (if on medical device itself it should be in a format that will not be dislodged during cleaning, disinfecting or sterilization of the device) or on the primary packaging of each unit or on the primary packaging of multiple devices should contain the following where applicable:

- Name and/or trademark of the manufacturer including the full address of the manufacturer. *Name and address of Authorised Representative or Distributor may be added but this additional label should not obscure any of the manufacturer's labels.*
- Manufacturer's product name with additional reference number or product code

- UDI code in accordance with the EU Council Directive 93/42/EEC (MDD) or EU Regulations 2017/745 (MDR).
- Type of product and main characteristics, i.e. details to identify the device and its use.
- If the packaging is not transparent, it must bear a diagram (preferably actual size) showing the essential parts of the product and indicating the position of the product in the packaging.
- Lot number prefixed by the word "LOT" (or equivalent harmonised symbol, if applicable)/batch code or serial number. Manufacture date should be additionally indicated.
- For products supplied sterile or for single use disposable devices, the label should clearly state STERILE and/or DISPOSABLE or SINGLE USE (or equivalent harmonised symbols). Additionally, a date of expiry is to be stated with clear indication to expiry year and month before which the device is considered to be safe to use. In order to verify the stated shelf life, the date of manufacture must be included in the label. Labels should include the used sterilization method where applicable.
- Information for particular storage conditions that apply (temperature, pressure, light, humidity, etc., as appropriate must be read in the package (or equivalent harmonised symbols).
- Information for handling (e.g. warnings) or instructions for use, if applicable (or equivalent harmonised symbols).

For devices that have CE marking approval, the CE mark should be on the item itself, or on the primary packaging as appropriate. Please note: if on device itself, this should not be removable during handling, use or cleaning of the device.

3.4. Shelf life

The shelf life of the device shall be clearly indicated. UNFPA will only accept devices complying with [TRS 1025 - Annex 8: Points to consider for setting the remaining shelf-life of medical products upon delivery.](#)

For sterile products, the expiration date should not exceed 5 years from the date of sterilization.

3.5. Instruction for use/product manuals

Instructions for use or manuals must be provided in the following languages or as specified: English, Spanish or French, as per request based on the recipient country of distribution. This should include any assembly instructions.

3.6. Other requirements

3.6.1. Installation, spares and service

In addition to installation details, information should be provided on service, repair and spares where applicable. Any special tools or test equipment required should also be specified at both bid stage and Purchase Order stage.

3.6.2. Training and support

For equipment where training is required before competent technical staff can use the device, this should be clearly indicated at the bid stage and also at Purchase Order stage with information of who will provide this training.

3.6.3. Warranty

A copy of warranty should be provided for all equipment.

3.6.4. Re-usable products

Clear information/instructions should be provided on cleaning, disinfection and sterilization methods and types for the device. The method should be adapted to the local constraints of the countries or region the device is intended to be used.

3.6.5. Electrical devices

The available voltage and plug types should be specified and if contracted, the correct voltage and plug type should be supplied for the respective country of destination as per Purchase Order.

Photo of model's identification plate.

3.6.6. Disposal of the device

Where appropriate, the necessary information shall be provided for the safe disposal or decommissioning of the device after its recommended time of use. Note: some specific regulation may locally apply.

3.6.7. Hazardous products

Where appropriate, the necessary information shall be provided for the product hazardous classification and material safety data sheet (MSDS).

3.7. Environmental Management Systems

Manufacturers are encouraged to provide v

Manufacturers are requested to provide proof of ISO 14001 (Environmental Standard) and ISO 50001 (Energy Standard) certification. If ISO 14001 is not available, a signed letter is required from a manufacturer stating that if they will be awarded with a global LTA with UNFPA, they commit to complete the ISO 14001 certification process before the end of first year of LTA validity.

Proof that carton and paper material used by the manufacturer is FSC (Forest Stewardship Council) certified, if available. (From both manufacturer and distributor).

Special Note:

1. *All documents submitted must be in English or be accompanied with certified translation.*

List of required documents

a) Manufacturer documents/QMS

List of documents:

- i) ISO 9001 – Quality Management Systems: Requirements*
- ii) ISO 13485 – Medical Devices: Quality Management Systems*
- iii) Manufacturer shall provide a post-market study report covering the last 3 years. Product document*
- iv) A copy of the latest audit report by an European health product distributor, if available.*
- v) ISO 14001 (Environmental Standard) and ISO 50001 (Energy Standard) certification, if available*
- vi) Declaration of conformity to applicable regulation(s) and/or standard(s) according to the model given in ISO/IEC 17050*
- vi) Evidence of legal registration to manufacture the particular device by the respective national regulatory authority and valid manufacturing licences.*

b) Product documents (we need to indicate how they should name folder for each product)

List of documents:

- i) QNR for MDs*
- ii) QNR for EI Battery-Operated Devices, if applicable*
- iii) Declaration of conformity to applicable regulation(s) and/or standard(s)*
- iv) Evidence that the product has been cleared by the relevant regulatory authorities to market in Europe or the U.S, or in other IMDRF representative countries*
- v) For CE marked products, the manufacturer shall provide EC Representative (EC Rep) contact details and Country.*
- vi) Evidence of clinical studies to all but class I non-sterile, non-measuring medical devices e.g a copy of the study results.*
- vii) Post Market Surveillance evidence and reports appropriate for the device class in accordance with EU MDD/MDR requirements.*
- viii) If available, third party laboratory test reports (declaring the name of laboratory and accreditation status) shall be submitted as part of the medical device dossier.*

ix) *For sterile products: the manufacturer itself or any **contract sterilizer** company shall provide evidence of compliance to :*

(1) ISO 11135 (ETO sterilization)

(2) ISO 11137 (Gamma Irradiation)

(3) ISO 17665 (Steam sterilization)

(4) ISO 20857 (Dry heat)

(5) ISO 14937 (for any other sterilization method)

x) *Copies of certificates of sterilization from the last 3 most recently released batches from the manufacturer*

xi) *Evidence of compliance to storage and transportation of sterile products. Data loggers reports shall be included in shipments containing sterile medical devices as relevant*

xii) *Photos of primary and secondary packaging shall be provided accurately representing the product UNFPA will receive*

xiii) *Photos of primary and secondary labelling shall be provided accurately representing the product UNFPA will receive.*

Note : Information marked on the package label shall comply with the requirements as described under Section 3.3.

xiv) *The shelf life of the device shall be clearly indicated*

xv) *Instructions for use or manuals in English, French and Spanish must be provided*

xvi) *For equipment items:*

(a) Instructions for use or manuals

(b) Information on installation details, training, service, repair and spares where applicable.

(c) A copy of warranty should be provided for all equipment.

xvii) *For Reusable Products : Clear information/instructions should be provided on cleaning, disinfection and sterilization methods and types for the device.*

xviii) *For Electrical Products : The available voltage and plug types should be specified*

xix) *Disposal of the device : the necessary information for the safe disposal or decommissioning of the device after its recommended time of use.*

xx) *Where appropriate, the necessary information shall be provided for the product hazardous classification and material safety data sheet (MSDS).*