

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 stand point, 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).

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**.

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 licenses and or a Free Sales Certificate.

Any official clearance or legal certificates, (e.g. 510k clearance, CE certificates, or equivalent licences shall be provided, where applicable).

The necessary information and documentation to be provided in the submission are outlined in Annex I and Annex II attached.

¹"Manufacturer" means any natural or legal person¹ 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*

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

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

4. Conformity of products with specific safety / performance standards

4.1. List of applicable standards

The standards to which the device is claimed to be compliant to should be part of a list of local recognized standards (e.g., EC list of harmonized standard, 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 to be supplied.

4.2. Sterile products:

4.2.1. 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.

4.2.2. 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.

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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.

4.3. 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.

NOTE *UNFPA and other UN agencies will from 2014 going forward require that all paper and cardboard secondary packing is FSC marked. Similarly, UNFPA will gradually between 2014-2020 increase its requirement for the use of recycled material in secondary packing. Plastic used in secondary packing will gradually be required to be fully biodegradable.*

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.

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 address of the manufacturer. *Name and address of Authorised Representative or Distributor maybe added but this additional label should not obscure any of the manufacturer's labels.*
- Manufacturer's product reference.
- 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.
- For products supplied sterile or for single use disposable devices, a date of when the device may be safely used with year and month should be clearly indicated including the sterilization method where applicable. In order to verify the stated shelf life, the date of manufacture should be provided.
- Information for particular storage conditions that apply (temperature, pressure, light, humidity, etc., as appropriate (or equivalent harmonised symbol.)
- Information for handling, if applicable (or equivalent harmonised symbol).

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.

4.4. Shelf life

The shelf life of the device shall be clearly indicated. Devices with less than 75% shelf life will not be accepted by UNFPA.

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

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4.5. 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 recipient country of distribution. This should include any assembly instructions.

4.6. Other requirements

4.6.1. 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.

4.6.2. 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.

4.6.3. Warranty

A copy of warranty should be provided for all equipment.

4.6.4. Re-usable products

Clear information/instructions should be provided on cleaning, disinfecting 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.

4.6.5. 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.

4.6.6. 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

4.7. Environmental Management Systems

Manufacturers are encouraged to provide ISO 14001 certification.

Manufactures will – over time - be requested to provide proof of ISO 14001 (Environmental Standard) and ISO 50001 (Energy Standard) certification. It is therefore encouraged, but not required before 2015-16, to have these certifications in place.

Special Note:

1. *All submissions should include details of the medical device quality assurance process of the submitter of the documentation including completed questionnaire (Annex I) if applicable and completed checklist (Annex II) with the attached documents.*
2. *All documents submitted must be in English or be accompanied with certified translation.*

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Annex I: Medical Equipment Questionnaire

Please note: **ONLY** complete this form (Annex I) for electrical or battery operated equipment.

PART I – Submitter and device identification

Device Identification (Trade name, Type, Model, Reference(s)):

Identification of the submitter:

Name:

Address:

Status:

Legal manufacturer:

Or

Distributor – Trader

If the Submitter is not the legal manufacturer, then indicate the legal manufacturer:

Device category: (Generic group of devices):

Device classification (specify the related regulation, e.g. MDD, FDA, Other)

93/42/EEC directive:

Class:

Rule# (according to MDD annex IX):

FDA:

Product code:

Regulation number:

Product class:

Other regulation (specify):

Nomenclature code (if known – specify GMDN, UMDNS or other):

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Part III – Regulatory certification

Is the **device EC marked**? Yes No

For devices other than Class I, and Class I sterile devices / Class I with measuring function:

Nature of the EC certification (MDD 93/42/EEC): Annex II.3 Annex V

Identification of the Notified Body (+ identification number):

Is the device **FDA approved**? Yes No

For FDA Class I device: Manufacturer name:

Manufacturer listing #:

If the device is “510k cleared”, indicate the 510k clearance #:

Other regulatory clearance / registration (specify Canada, Japan, Australia, ...):

Applicable regulation:

Certification / license number:

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Part IV - compliance to technical standards

If the declaration of compliance is based on report(s) issued by an independent testing laboratory, the reference of the test report must be indicated (mandatory for safety compliance of electro-medical devices)

Standard # and date	Fully or partially applied	Identification of the Testing laboratories, where used	Test report reference

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Part V – Other information

V-1 INSTALLATION / SPARES / SERVICE

1. Is installation necessary? Yes No

Specify tools required (if Yes):

2. Is training required? Yes No

Specify who will provide training and specify costs if applicable:

3. Are spare parts available? Yes No

Specify source and if additional costs required:

Specify period supply of spare parts is guaranteed:

4. Information available on service/maintenance? Yes No

Attach information:

5. Specify voltage available:
Specify plug supplied:

V-2 DECONTAMINATION

Only for re-usable devices.

1. Specify method for cleaning:
2. Specify instructions for disinfection:
3. Specify any restrictions on detergent/disinfectant types:
4. Specify sterilization method required before re-use:

V-3 WARRANTY

Specify recommended maximum number of uses or years of use or period of use:

V-4 SAFE DISPOSAL

Specify instructions for safe disposal:

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Annex II: Checklist of Required documentation

Documents to be submitted (**where applicable**) and must be true and valid copies:

- A. Copy of manufacturing licence
- B. Letter of authorization to act on behalf of manufacturer if submission is not from the manufacturer
- C. Copy of ISO 9001: 2008 Certificate (for manufacturer and for trader)
- D. Copy of ISO 13485:2003 Certificate (for manufacturer and for trader)
- E. Copy of ISO 14001:2004 Certificate (for manufacturer and for trader)
- F. Copy of ISO 50001:2011 Certificate (for manufacturer and for trader)
- G. Declaration of conformity (specifying the relevant standard and attaching copy of certificate)
- H. CE certificate
- I. 510k Premarket approval device letter/ Device licence (Australia, Japan, Canada)
- J. Complete and detailed technical specifications of the product
- K. Product technical data sheet providing photo of the product at various angles if necessary
- L. Instruction for use in English, Spanish and French
- M. Installation manual
- N. Service/repair information
- O. Information on cleaning, disinfecting and sterilization methods and types to be used (for reusable devices only)
- P. ISO 7153-1
- Q. Certificate of sterilization
 - ISO 17665 (Steam sterilization)
 - ISO 11135 (ETO sterilization)
 - ISO 11137 (Gamma Irradiation)
 - Other (Specify :)
- R. ISO 14001
- S. Quality Assurance process (for the manufacturer and/or for the trader)

T. Specify any other documentation provided (e.g. any test results or relevant standards):

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U. Other relevant certificates related to Environmental and/or Energy management.