

Annex 4

TECHNICAL REQUIREMENTS FOR IN-VITRO DIAGNOSTICS

1. Eligibility criteria

This document serves to give guidance to the technical requirements for UNFPA procurement of In-Vitro Diagnostics Medical Devices (IVDs). 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, where applicable additional requirements will be included for IVDs.

The technical requirements also apply when the submitter is not the legal manufacturer¹(i.e.: a distribution company). In this case, a letter from the manufacturer authorising the supplier will be required (Annex 18). These requirements apply to IVDs procured either as stand-alone items or as part of a kit.

2. General guidance and requirements

2.1. International Guidance

All in-vitro diagnostics (IVD) must be WHO prequalified where the type of IVD is subject to WHO prequalification mandate or be approved and marketed by one of the five founding members of the GHTF (the same regulatory version submitted should be clearly communicated). Suppliers shall conform to the QMS standard: ISO 13485:2016 Medical devices - Quality management systems -- Requirements for regulatory purposes.

The following guidance shall be taken into consideration by the manufacturer:

- IMDRF/GRRP WG/N47 FINAL:2018: Essential Principles of Safety and Performance of Medical Devices and IVD Medical Devices

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 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*

- IMDRF/IVD WG/N64FINAL:2021: Principles of In Vitro Diagnostic (IVD) Medical Devices Classification
- GHTF/SG1/N78:2012: Principles of Conformity Assessment for Medical Devices
- ISO 14971:2019 Medical devices – Application of risk management to medical devices

For more information on IMDRF, refer to the IMDRF website: <http://www.imdrf.org/>.

2. 2. Declaration of Conformity

The IVDs shall conform to relevant International Organisation for Standardisation (ISO) standards for suppliers/manufactures of medical devices and risk management. 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 directives for which the compliance is declared. Declaration of conformity is a legally binding document.

2. 3. Regulatory Requirement Compliance

IVDs 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) must comply with EU Council Directive 98/79/EEC (IVDD) or EU Regulations 2017/746 (IVDR) with valid EC Certificate and Declaration of Conformity for the CE mark applied.

Note: For manufacturers which are supplying CE certificates and relevant documentation under the IVDD, a declaration letter from the manufacturer that it is working towards compliance to IVDR is required. Additionally, the manufacturer shall submit objective evidence to demonstrate compliance to IVDR within one (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.

In case of a long-term agreement (LTA), suppliers shall notify to UNFPA any major product modification, such as branded name, marketing clearance or any approval certification.

2. 4. Quality Management System standards

The manufacturer 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

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).

3. Product information

3.1 Product specification and performance

The IVDs proposed under this bid should clearly state:

- Type of diagnostic assays
- Type of specimen the diagnostic is intended to be use on/for
- Appropriate point of care and data supporting use at this point of care
- Sensitivity and specificity studies of the diagnostic

3.2 Stability studies

Stability studies should indicate the claimed shelf life of the IVD, in-use stability and shipping studies. These studies must reflect the environmental conditions of the countries the IVD is intended to be supplied. The information provided must include a justification for the anticipated conditions The stability studies information provided under this section must be consistent with the instructions for use and product labels provided within the product.

3.3 Shelf-life

Guaranteed shelf life upon delivery differs from shelf life upon manufacture. It is important to specify the required shelf life upon delivery in the bid solicitation documents. For IVDs, UNFPA requires that the reagents will have a shelf life complying with https://www.who.int/docs/default-source/medicines/norms-and-standards/current-projects/qas_20_864_rev1_shelf_life_emergency_health_kits.pdf?sfvrsn=e2c5c188_3

4. Labelling

Labelling shall be associated with the IVD and where applicable shall imply labels on product, instructions for use (IFU), the instrument manual and any other instructional materials provided to the user.

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.

These labels must minimally include the following information:

- the product name and product identification number (product code/catalogue number in accordance with the EU Council Directive 93/42/EEC (MDD) or EU Regulations 2017/745 (MDR)
- the name and contact details of the manufacturer, or an authorized representative of the manufacturer, on the outer package labels
- the name of the reagent/ingredient
- the expiry date
- an indication of any special storage and/or handling conditions that apply
- the warnings and precautions
- the lot/batch and/or serial number
- the information regarding particular product conditions such as product sterility
- the names of all included reagents in each box on the outer package label, where possible.

Where a component is too small to contain all the above information, it must at a minimum contain:

- name

- lot number expiration date
- volume
- storage conditions.

Additionally, the Instruction for use should include (but not limited to):

- A clearly stated intended use, including:
- what is detected by the assay (that is, the analytical use of the assay, e.g. the marker or nucleic acid sequence being detected
- the clinical indication for the test
- the function of the product
- the intended user
- intended testing population etc
- an indication that the product is for in vitro use.
- A general description of the principle of the assay method or instrument principles of operation.
- If applicable, a description of the accessories, and other products that are intended to be used in combination with the product but are not provided with the product.
- Storage conditions, including storage conditions and stability of both the unopened and opened product, and working solutions. When applicable, these instructions should include such information as conditions of temperature, light, humidity, and other pertinent factors.

Symbols used in In-vitro Diagnostics labelling and information to be supplied (e.g., Information For Use leaflet) shall comply with the current version of ISO 15223 Part 1.

Where applicable labelling on an IVD itself should be in a format that will not be dislodged during cleaning, disinfecting or sterilization of the device.

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).

5. Packaging

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 shall be provided accurately representing the product UNFPA will receive.

Outer cartons shall be numbered consecutively. No carton may contain items from more than one manufacturing batch. Cartons containing non-uniform contents must be specially marked with red at the top corners.

6. Storage and transportation of temperature sensitive

IVDs requiring controlled temperatures during storage and transportation shall be provided in accordance with the Model guidance for the storage and transport of time- and temperature-sensitive pharmaceutical products, WHO TRS 902, Annex 9, Appendix 2 [Annex 9 Guidelines on packaging for pharmaceutical products](#)

Keep cool items shall be packed/stored/transported separately and in accordance with temperature requirements for such items. To maintain the desired temperature during transportation container(s) with dry ice, reefer containers or thermal jackets may be used. Such containers should protect the product from mechanical damage and any anticipated ambient temperature range during transportation and transit; they shall be tamper-proof and allow for the recipient to establish that the product has not been tampered with while in transportation and transit.

Temperature in the container(s) during transportation and transit shall be monitored using appropriately calibrated monitoring devices.

Compliance with the required temperature conditions shall be demonstrable to UNFPA and records shall be kept as per Good Distribution Practices, [WHO good storage and distribution practices for medical products](#), Annex 7, WHO Technical Report Series 1025, 2020.

7. Other requirements

7.1 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 Order stage.

7.2 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 Order stage with information of who will provide this training.

7.3 Warranty

A copy of warranty should be provided for all equipment.

7.4 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.

7.5 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.

7.6 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.

7.7 Disposal of the device

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

8. Environmental Management Systems

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 BPA with UNFPA, they commit to complete the ISO 14001 certification process before the end of the first year of LTA validity.

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

9. Documentation to be submitted with each Offer

(Please note that the list of documents here is not exhaustive, refer to the respective questionnaire for additional information on supporting documents to be submitted)

1	WHO PQ	WHO PQ accolades/Certification
2	QMS standards	Valid ISO 13485 certificate for the legal manufacturer. (English Copy).
3	Product standards	As described in the technical product specifications.
4	Marketing approval	Valid certificate from one of the five founding members of the GHTF (same regulatory version to be submitted): The certificate shall indicate: a. Name of regulatory authority b. Market approval/clearance with number

5	Product documentation	<p>c. Claimed product intended use.</p> <p>d. Supplier's product code (catalogue number) & short description.</p> <p>e. Manufacturer's product code (catalogue number) & short description.</p> <p>f. Supplier's contact details, including link to web site with product catalogue.</p> <p>g. Manufacturer's contact details, including link to web site with product catalogue.</p> <p>h. Contact details of the person appointed for post-market surveillance including vigilance, customer complaints and recalls.</p> <p>i. Complete technical product specification (technical data sheet).</p> <p>j. List of all supporting items/devices required, but not supplied.</p> <p>k. Recommended temperature and humidity for shipping, storage and use/operating.</p> <p>l. Instructions for use (IFU), brochure and training material in English, French or Spanish.</p> <p>m. Installation and training and follow up service and maintenance.</p> <p>n. Published field testing studies not older than 2 years.</p> <p>o. Estimated weight and volume.</p> <p>p. Photos of primary and secondary packaging with readable label information.</p>
6	Product lot release	As described in the technical product specifications.
7	Hazardous goods	Hazardous classification (including MSDS), as described in the technical product specifications