

UNICEF TECHNICAL REQUIREMENTS FOR IN VITRO DIAGNOSTICS (IVD)

February 2016

This document was developed for suppliers and products to comply with, in the context of UNICEF Quality Assurance (QA) Policy for procurement and supply. It adopts the guidance of the International Medical Device Regulators Forum (IMDRF)¹ to ensure safety performance, quality and equality in our procurement processes of medical devices, including in vitro diagnostics (IVDs).

Technical requirements framework

1. World Health Organization (WHO) pre-qualification (PQ) award:

Products must be WHO prequalified where the type of IVD is subject to WHO prequalification mandate.

2. Conformity with Quality Management System (QMS) standards:

Suppliers²/Manufacturers shall conform to the following QMS standard: ISO13485: Medical devices - Quality management systems -- Requirements for regulatory purposes.

IVD products purchased by UNICEF from suppliers shall be produced and controlled in accordance with internationally recognised standards for assuring safety, quality and performance of IVDs.

N.B. – UNICEF is aware of the changes being implemented by the European Union (EU) with regards to the Medical Devices and IVDs Directives. As these changes take shape and the new Regulations are adopted and implemented by Notified Bodies and subsequently Certifying Bodies, UNICEF reserves the right to request information from current or future suppliers on how they plan to accommodate the changes so that appropriate International Organisation for Standardisation (ISO) certification is maintained.

3. Conformity with product standards:

a. The manufacturer should hold the product technical documentation as per the IMDRF/GHTF requirements (goods that do not meet these standards shall not be acceptable to UNICEF):

SG1/N68:2012	Essential Principles of Safety and Performance of Medical Devices
SG1/N11:2008	Summary Technical Documentation (STED) for demonstrating conformity to the Essential Principles of Safety and Performance of Medical Devices
SG1/N45:2008	Principle of In Vitro Diagnostic (IVD) Medical Devices Classification
SG1-N70:2011	Label and Instructions for Use for Medical Devices

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

- b. The product(s) shall conform to relevant International Organisation for Standardisation (ISO) standards for suppliers/manufactures of medical devices and risk management.
- c. The labelling of the product shall meet the requirements as described in the in the below standards and guidance documents:

ISO 18113-1:2011	In Vitro Diagnostic Medical Devices - Information Supplied by the Manufacturer (Labelling) - Part 1: Terms, Definitions and General Requirements
ISO 18113-2:2011	In Vitro Diagnostic Medical Devices. Information Supplied by the Manufacturer (Labelling) - Part 2: In Vitro Diagnostic Reagents for Professional Use
ISO 18113-3:2011	In Vitro Diagnostic Medical Devices - Information Supplied by the Manufacturer (Labelling) – Part 3: In Vitro Diagnostic Instruments for Professional Use
ISO 18113-4:2011	In Vitro Diagnostic Medical Devices – Information Supplied by the Manufacturer (Labelling) – Part 4: In Vitro Diagnostic Reagents for Self-Testing
ISO 18113-5:2011	In Vitro Diagnostic Medical Devices – Information Supplied by the Manufacturer (Labelling) – Part 5: In Vitro Diagnostic Instruments for Self-Testing
ISO 15223-1:2012	Medical Devices – Symbols to be Used with Medical Device Labels, Labelling and Information to be Supplied
GHTF SG1 N70:2011	Label and Instruction for Use for Medical Devices
IMDRF/UDIWG/ N7FINAL: 2013 UDI	Guidance: Unique Device Identification (UDI) of Medical Devices

- d. The product shall be assessed by at least one of the 5 below regulatory authorities (or at minimum with SG1-N70:2011: Label and Instructions for Use for Medical Devices):

European Union	Regulatory agency in the European countries;
USA	Food and Drug Administration (FDA).
Canada	Health Canada;
Australia	Therapeutic Goods Administration (TGA);
Japan	Japan Ministry of Health, Labour and Welfare

- e. Any test registered for “Research Use Only” or “For export only” is not acceptable, unless specifically authorised in writing by UNICEF.

4. Product(s) compliance with regulatory requirements for marketing approval:

Product(s) shall be authorised/cleared by at least one of the 5 above mentioned regulatory authorities and comply with the corresponding pre-market requirements (listed below) as described in the GHTF for marketing approval/clearance³:

European Union	EC Full Quality Assurance Certificate EC Production Quality Assurance Certificate
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³ Source: Abbreviated prequalification assessment. Accessed on: January 21st, 2016
http://www.who.int/diagnostics_laboratory/evaluations/140530_pgdx_173_abbreviated_assessment_v1_final_buffet.pdf

	EC Type-Examination Certificate
US Food and Drug Administration	PMA letter or BLA license
Health Canada	Medical Device Licence and summary report for a Class IV IVD CMDCAS-issued ISO 13485 Certificate
Therapeutic Goods Administration, Australia	TGA Licence for Manufacture TGA Issued ISO 13485 Certificate AUST R Number TGA Full Quality Assurance Certificate TGA Type-Examination Certificate TGA Production Quality Assurance Certificate
Japan Ministry of Health, Labour and Welfare	JMHLW Minister's Approval JMHLW License for Manufacturer (seizo-gyo-kyoka) JMHLW Recognised Foreign Manufacturer (gaikoku seizo-gyosya nintei)

5. Product(s) shelf life:

- a. The supplier shall provide the total product shelf life in months (as applicable).
- b. The supplier shall ensure that a minimum of two thirds of the shelf life remains at delivery.
- c. Only in special circumstances UNICEF may accept shorter shelf life.

6. Product(s) lot release:

The supplier shall provide lot release certificates for each lot delivered to UNICEF:

- a. For products classified under class D⁴ (high individual risk and public health risk) a lot release certificate obtained from a Conformity Assessment Body (CAB) shall be submitted to UNICEF.
- b. For malaria rapid diagnostic tests (RDTs), a laboratory quality control lot testing report obtained in accordance with the WHO Lot testing programme for malaria rapid diagnostic tests, shall be submitted to UNICEF⁵.

7. Hazardous goods:

The supplier shall provide the material safety data sheet (MSDS) issued by the manufacturer, including Section 14: Transport information, completed (as applicable).

8. Product(s) modifications:

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

9. Sustainability goals:

As UNICEF moves towards the implementation of the Sustainable Developmental Goals, it is keenly interested in the efforts made by manufacturers and suppliers towards sustainable initiatives. Thus, as an asset, but not a requirement, the supplier is encourage to provide information on the implementation of sustainability in the production and distribution phases of the procurement process with an emphasis on social and environmental responsibilities.

⁴ GHTF document: SG1-N45:2008: Principle of In Vitro Diagnostic (IVD) Medical Devices Classification. Available at: <http://www.ghf.org/documents/>

⁵ WHO/FIND Lot testing programme for malaria rapid diagnostic tests documents, available at: http://www.wpro.who.int/sites/rdt/who_rdt_evaluation/lot_testing.htm

Attachments that shall be submitted with the offer

1	WHO PQ	WHO PQ award
2	QMS standards	Valid ISO 13485 certificate for the legal manufacturer. Copy in English.
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: <ul style="list-style-type: none"> a. Name of regulatory authority b. Market approval/clearance with number
5	Product documentation	<ul style="list-style-type: none"> c. Claimed product intended use. d. Supplier's product code (catalogue number) & short description; e. Manufacturer's product code (catalogue number) & short description; f. Supplier's contact details, including link to web site with product catalogue; g. Manufacturer's contact details, including link to web site with product catalogue; h. Contact details of the person appointed for post-market surveillance including vigilance, customer complaints and recalls. i. Complete technical product specification (technical data sheet); j. List of all supporting items/devices required, but not supplied; k. Recommended temperature and humidity for shipping, storage and use/operating; l. Instructions for use (IFU), brochure and training material in English, French or Spanish; m. Installation and training and follow up service and maintenance; n. Published field testing studies not older than 2 years; o. Estimated weight and volume; p. Photos of primary and secondary packaging with readable label information.
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
8	Sustainability goals	Indicate the company's efforts to implement any of the following in the coming 12 months: <ul style="list-style-type: none"> a. <u>Environmental management</u>: Plans to obtain the Environmental Management System certificate ISO 14001 or equivalent with CO₂ reduction targets. Specify which areas will be covered. b. <u>Standards</u>: Plans to conform to the Standards of Social Accountability e.g. SA8000 or ISO 26000, or other standards that demonstrate commitment to sustainability issues. Specify which areas will be covered. c. <u>Global initiatives</u>: Plans to join the Global Reporting Initiative and/or the United Nations Global Compact. d. <u>Other related information</u>: Other plans related to sustainable production/distribution.