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Empowered lives. Resilient nations.	**Title:**	**UNDP TECHNICAL & REGULATORY REQUIREMENTS FOR IN VITRO DIAGNOSTIC DEVICES (IVDs)**		
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Abbreviations

CAB- Conformity Assessment Bodies
DOC- Declaration of Conformity
EUA Emergency Use Authorization
ERPD - Expert Review Panel for Diagnostics
RA – Regulatory agency
RDT- Rapid Diagnostic Test
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
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 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.

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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 (MD), 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 IVDs and Rapid Diagnostic tests (RDTs). 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 health products mentioned above. The intended audience includes country offices, QA team, GPU, and others in the procurement process. The UNDP's procurement entity must share this document with bidders as a part of the solicitation process to ensure compliance with UNDP's expectations regarding the safety and quality of the medical products.

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 IVDs 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 in Vitro Diagnostic Regulation (IVDR) 2017/746. 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.

4. Scope

The scope includes technical and regulatory requirements that the bidders must comply with and for the IVD products to conform to as per the UNDP's QA Policy for Health Products[1]. The products covered under the scope of this document are IVDs, including IVD analyte-specific reagents for tests, IVD instruments, general

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purpose IVD instruments including hardware, software and their accessories, sample processing equipment, IVD generic use consumables, stand-alone software as an IVD etc. An exhaustive list of IVDs could be found at European Medical Device Nomenclature (EMDN) website[2].

5. General References

This document is based on the International Medical Device Regulators Forum (IMDRF) classification of *in vitro* diagnostics (See annex I). The classification of IVDs mentioned in this document is based on the IMDRF proposed document 'Principles of In Vitro Diagnostic (IVD) Medical Devices Classification IMDRF/IVD WG (PD1)/N64'.

a) IMDRF/GRRP WG/N47 FINAL:2018 Essential Principles of Safety and Performance of Medical Devices and IVD Medical Devices
b) IMDRF code: IMDRF/RPS WG/N13FINAL:2019 (Edition 3) - 21 March 2019 - In Vitro Diagnostic Medical Device Market Authorization Table of Contents (IVD MA ToC)
c) IMDRF Code IMDRF/RPS WG/N9 - 21 March 2019 - Non-In Vitro Diagnostic Device Market Authorization Table of Contents (nIVD MA ToC)
d) IMDRF/GRRP WG/N52 FINAL, Principles of Labelling for Medical Devices and IVD Medical Devices: 2019
e) GHTF/SG1/N046:2008 - Principles of CA for IVD 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 IVDs

6.1. Requirements for products for market clearance

Annexes II shows a typical list of conformity elements for IVDs 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 IVD.

Class A devices (excluding sterile items)
IVDs that fall under Class A (non-sterile) shall have registration in the country of manufacture. All CE Self-certified class A non-sterile IVDs shall be compliant with IVDR 2017/746.

Class A (sterile items), Class B, C, and D devices
IVDs offered to UNDP must comply with regulatory requirements listed below under a & b.

a) The IVDs offered to UNDP shall have market clearance from at least one of the regulatory agencies in the GHTF founding member countries mentioned below:

- Australia: Therapeutic Goods Administration (TGA) Device Licence for both IVDs and Medical devices

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

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- Canada: Device Licence, Medical Devices Regulations (SOR/98-282) for both IVDs and medical devices
- European Union: IVDD 98/79/EC to IVD Regulation (EU) 2017/746 for *in vitro* diagnostic medical devices (IVDR). Existing devices other than class A non-sterile that comply with Directive 98/79/EC may still be placed on the market during transitional periods under certain conditions. 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 IVDs, the device manufacturers shall be registered with FDA and devices shall be listed with FDA. Proof the same shall be provided.

b) The IVD shall be prequalified by World Health Organization (WHO) and holds a valid PQ number as per latest list of prequalified IVDs[3]. UNDP recognizes the WHO prequalified in vitro diagnostics (IVDs) for procurement purposes, relying on the declaration of equivalence as outlined in Annex III.

c) In the event of short supply or public emergency or for certain donor-funded projects, UNDP may consider IVDs with the following regulatory requirements.

- The IVD has an Emergency Use Authorization (EUA) from one of the GHTF founding member accompanied with a Declaration of equivalence as per Annex IV.
- assessed and advised by WHO Expert Review Panel for Diagnostics (ERPD).

Bidders shall not offer IVDs with EUA and/or ERPD unless requested by UNDP procurement entity. UNDP QA reserves the right to ask for supplementary information on such offers under ERPD and/or GHTF EUA.

6.2. Requirements for manufacturing sites

Quality Management System (QMS) standards: Bidders, 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:

a. For products classified as IVDs: Manufacturers shall comply with the ISO 13485 QMS or US FDA 21 CFR 820 QSR or the GHTF founding country's version of the ISO 13485 standard or Medical Device Single Audit Program (MDSAP) audit conducted by a recognized auditing organization by the GHTF founding countries. The ISO 13485 certificate should be issued from a Conformity Assessment Body (CAB) accredited to carry out conformity assessment by the accreditation authorities recognized by the regulatory authorities in one of the GHTF founding member countries. The scope of the certificate shall cover the product type/ services/activity offered (e.g., design & development, production and

[3] Prequalified In Vitro Diagnostics https://extranet.who.int/pqweb/vitro-diagnostics/vitro-diagnostics-lists

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distribution of reagents and instruments for in vitro diagnostic use in biochemistry, serology, blood grouping, microbiology etc).

b. 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).
c. Where the manufacturer chooses 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.
d. If the health products offered to UNDP are approved based on WHO-prequalified status or Emergency Use Authorization (EUA), bidders shall submit a declaration of equivalence for each product regarding its prequalification/ status as per the template provided in Annex III&IV. UNDP reserves the right to ask for additional documents according to defined procedures. The bidder will supply the product as declared in Annex III OR IV- equivalence declaration for health products submitted based on the WHO prequalification OR EUA status Ver 01.

6.3. Requirements for Bidders

Bidders who 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 IVDs.

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.

6.4. Requirements for Rapid Diagnostic Tests (RDTs)

UNDP only procures Rapid Diagnostic tests (RDTs) that are consistent with WHO guidance. For Tuberculosis, UNDP only procures products that are recommended for use by the WHO consolidated guidelines on tuberculosis, module 3: diagnosis[4]. RDTs for HIV, tuberculosis, hepatitis B, hepatitis C and syphilis co-infections as well as HPV and G6PD deficiency must meet the requirements mentioned in sections 6.1 to 6.3.

UNDP will not accept self-certified IVDs that present high individual or public health risk.

6.5. Product Documentation

Bidders 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:

[4] https://tbksp.org/en/guidance-books-solr

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6.5.1 Device Description[5]

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.

6.5.2 Product specification

Details such as size, dimension, weight of the item, features, and performance attributes of the IVD, 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.

6.5.3 Software as IVD

All software that meets the definition of an IVD 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.

6.5.4 RUO Products

Any IVD marketed as "Research Use Only (RUO)" will be scrutinized by UNDP and additional documents may be requested for review. Bidders shall not offer RUO products unless it is specifically requested by UNDP requesting entity.

6.5.5 IVDs requiring Product(s) lot release

[5] Summary Technical Documentation for Demonstrating Conformity to the Essential Principles of Safety and Performance of Medical Devices (STED) Study Group 1 Proposed Document SG1(PD)/N011R20

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For products classified under Class D (high individual risk and high public health risk), the bidder shall provide lot release certificates from a Conformity Assessment Body (CAB) for each lot delivered to UNDP. For malaria rapid diagnostic tests (RDTs), a lot testing report obtained in accordance with the WHO Lot testing programme for malaria rapid diagnostic tests, shall be submitted to UNDP6.

6.5.6 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 (printed on the primary packaging) 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%7. Any discrepancies regarding the above-mentioned remaining shelf life must be promptly communicated to the UNDP GPU country focal point.

6.5.7 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.

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

6.5.8 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 in vitro 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) as applicable, 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 IVD 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.

[6] https://apps.who.int/iris/handle/10665/338494

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

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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 IVD 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.

6.5.9 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 IVDD 98/79/EC or EU IVDR 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.

6.5.10 Hazardous goods

For devices that contain materials classified as "hazardous goods" or any kind of batteries or chemicals, 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.

6.5.11 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.

6.5.12 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.

6.5.13 Certificates

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

6.5.14 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.

7. Other requirements

7.1. 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 can be extended as per end-user's requirements and manufacturer's acceptance.

7.2. 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 end user.

7.3. 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.

7.4. 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, the equipment is safe for both patients and operators. Agreements can be established with bidders or manufacturers as per request.

Where applicable, information on service, repair, and spares shall be provided at the time of offer and training with regards maintenance (preventive and corrective) shall be provided. The bidders shall ensure that spares and consumable for a dedicated instrument/device shall be available during the entire life span of the instrument/device.

7.5. 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.

8. Documents to be submitted

Proof of all the technical 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 V for the check list for document submission. Bidder shall provide clarifications in the event of non-availability of proof/certificates for the product categories mentioned in Annex V. Depending on the foreseeable use of a product, the QA team might ask additional documents, as applicable.

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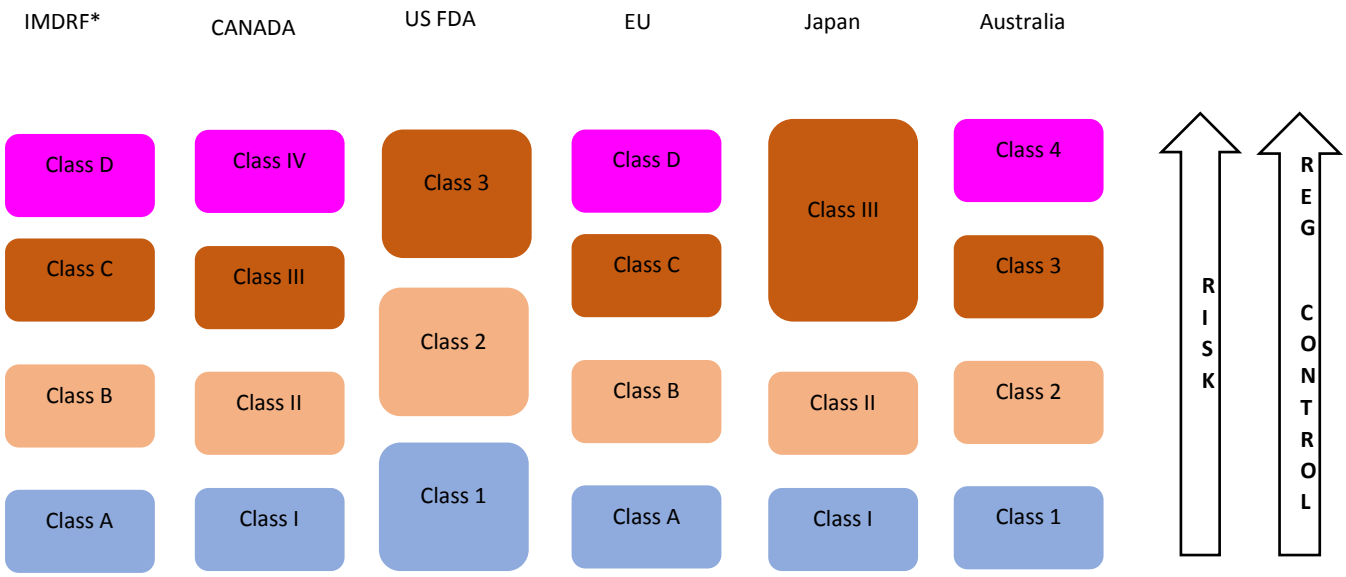
Annex I: Pictorial representation of IVD classification in GHTF founding member countries.

In vitro diagnostic devices showing the risk and regulatory control:



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Annex II List of conformity assessment elements required for IVDs (Guidance for Bidders and Manufacturers)

Conformity Assessment Elements	Class A	Class B	Class C	Class D	WHO PQed IVDs
QMS	ISO 13485 certificate or equivalent issued by a CAB recognised in one of the NRAs in the GHTF founding member countries. Full QMS or QMS excluding design and development controls	ISO 13485 certificate or equivalent issued by a CAB recognised in one of the NRAs in the GHTF founding member countries. Full QMS or QMS excluding design and development controls	ISO 13485 certificate or equivalent issued by a CAB recognised in one of the NRAs in the GHTF founding member countries. Full QMS	ISO 13485 certificate or equivalent issued by a CAB recognised in one of the NRAs in the GHTF founding member countries. Full QMS	WHO PAR and WHO PIR
Technical documentation	Yes	Yes	Yes	Yes	yes
Post-market surveillance procedures (made available upon request by UNDP)	Yes	Yes	Yes	Yes	Yes
Declaration of conformity (DOC) as per ISO 17050	Yes	Yes	Yes	Yes	No
Registration of the manufacturer and device by one of the founding GHTF country's RA	Yes	Yes	Yes	Yes	No
Copy of the valid manufacturing license	Yes	Yes	Yes	Yes	Yes
Certificate of marketing authorization or approval by one of the GHTF founding members (Refer section 6.1) or WHO PQ'ed with declaration of equivalence as per Annexe III or EUA with declaration of equivalence as per Annex IV	No	Yes	Yes	Yes	Yes
Proof of labelling as per regulations applied as per specific GHTF founding country's RA or as approved by the WHO PQ Team (Pictures of product, labels, ID plate, primary and secondary packaging etc)	Yes	Yes	Yes	Yes	Yes
MSDS	For hazardous goods or items supplied with battery or for reagents and chemicals	For hazardous goods or items supplied with battery or for reagents and chemicals	For hazardous goods or items supplied with battery or for reagents and chemicals	For hazardous goods or items supplied with battery or for reagents and chemicals	Yes
Product Lot release certificate from CAB	No	No	No	Yes	Yes for CLASS D and RDTs as applicable[8]

[8] Procedures for product testing and lot testing. Information for RDT manufacturers and procurers (who.int)

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Annex III: Declaration of equivalence for Health Products Submitted Based on WHO Prequalification and/or WHO EUA Status (Ver 01)

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

Name of the bidder		
Tick as applicable	Bidder	Manufacturer
Product Name and product REF as it appears on the label		
Product category (IVD, RDT etc)		
WHO prequalified report number		
Date of submission		

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

- The information and documentation supporting this dossier submission are true and correct per the latest edition of the WHO list of prequalified products.
- 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.
- The product's intended use is the same as detailed in the WHO report.
- The primary packaging and labelling information will be the same as listed in the product dossier assessed and inspected by WHO.
- There are no deviations in the product submitted from the WHO-prequalified product other than those shared in Table 1.

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

Difference[9]	Registered/WHO PQ Product	Product supplied to UNDP
Example: Labeling	*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.

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I declare that the product submitted by {Insert full company legal name here} is the same as the ones prequalified by WHO except for the minor deviations listed above.

Product name (as per labelling): _____

Product is prequalified from (WHO PQ)[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) AND/OR holds a EUA by WHO AND/OR EUA issued by the Regulatory Authorities of the Founding Members of GHTF. List all the market clearance as applicable.

WHO PQ Reference number: _____

Marketing authorization number/certificate, if applicable: _____

Marketing authorization country: _____

EUA listing agency/ Reference number: _____

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

Signature: _____

Name of authorized signatory:_____

Place: _____ Date: _____

[10]Prequalified In Vitro Diagnostics https://extranet.who.int/pqweb/vitro-diagnostics/vitro-diagnostics-lists

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Annex IV: Declaration of equivalence for Health Products Submitted Based on GHTF Founding Member EUA Status Only (Ver 01)

TO BE COMPLETED BY BIDDER IF ITEM IS EUA ONLY

Name of the bidder		
Tick as applicable	Bidder	Manufacturer
Product Name and product REF as it appears on the label		
Product category (IVD, RDT etc)		
EUA (Agency name, Date of authorization)		
Date of submission		

I, {Full name}, {Job title} at {Company's full legal name}, hereby confirm the following for the item under offer:

- The information and documentation supporting this dossier submission is true and correct as per the latest edition of the EUA summary issued and the EUA remain valid.
- The product name, the product code (REF), the regulatory version, manufacturing site {name here} will be the same as listed in the most recent EUA letter issued by the {agency name here}.
- The primary packaging and labeling information will be the same as listed in the product dossier assessed and inspected by the {agency name here}.
- There are no deviations in the product submitted from the EUA listed product other than the deviations shared in the below table 1.

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

Difference[11]	EUA Product	Product supplied to UNDP
Example: Labeling	*Spanish language*	*English language*

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

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I hereby confirm that the product submitted by {Insert full company legal name here} is the same as the ones authorized under EUA except for the minor deviations listed above.

Product name, REF (as per labeling):_____

Date EUA issued or last updated: _____

Most recent letter of authorization and the date of original EUA issued:_____

List the authorization Documents such as the Healthcare Provider (HCP) and Patient Fact Sheets and either the Manufacture Instructions/Package Insert (abbreviated to IFU) or the EUA Summary

:_____

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

Signature:_____

Name of authorized signatory:_____

Place: _____ Date: _____

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Annex V– Document Submission Checklist for Bidders, encompassing spares and consumables in the category of IVD (X indicates UNDP's mandatory requirements)

Serial No.	Type of information required from the bidder*	IVD	WHO PQ'ed IVD
	Technical documentation		
1	Product/Device description (Name, manufacturer's product REF as per labeling, trade name/brand, intended use, brochure, List of all supporting items/devices required, but not supplied, list of mandatory spares and consumables etc)	X	X
2	Product specification or technical data sheet	X	X
3	Unique Device Identifier (UDI), as applicable	X	N/A
4	List of applicable standards	list of claimed standards and certifications copy	N/A
5	Contact details of the person for post-market surveillance activities including vigilance, complaints and recalls	X	X
6	Pictures of the product with labelling clearly visible	X	X
7	Picture of the ID plate, for electrical and/or battery-operated equipment and instrument)	X	N/A
8	Pictures of the primary, secondary, and tertiary packaging with labelling clearly visible (all four sides)	X	X
9	Instruction for use and disposal	X	X
10	Recommended temperature and humidity for transport, storage, and use	x	x
11	Operation/User manual, as applicable	X	X
12	Barcode , wherever applicable	X	X
13	Certificate of analysis (made available upon request)	X	X
14	Shelf life	X	X
15	Supplier/bidder sales reference or LTA Holder items specific reference, wherever applicable	X	X
16	Lot release certificate	For class D from notified body	For class D from notified body. Lot testing report from a QC lab for Malaria RDTs.
17	MSDS	for dangerous goods or parts or chemicals	for dangerous goods or parts or chemicals
18	Declaration of equivalence (Annex III or IV, as applicable for the offer)	no	X
19	Voltage and plug type for electrical items	X	X
	Regulatory documents		
20	QMS for the manufacturer & critical subcontractor(s)	X	N/A
21	Market clearance certificate from any one of the 5 founding members of GHTF (Refer Section 6.1)	X	N/A
22	Declaration of conformity	X	N/A
23	Other applicable EU directives or equivalent for IVD instruments (EMC/LVD/REACH/RoHS/PED/TPED/machinery directive etc)	as applicable	N/A

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Serial No.	Type of information required from the bidder*	IVD	WHO PQ'ed IVD
24	Copy of the registration of device (listing) and manufacturing facility	X	N/A
25	Copy of the manufacturing license from the manufacturer	X	N/A
26	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 IVDD	x	N/A
27	For all items classified as "software as IVD," compliance to the following standards is necessary. • IEC/ EN 62304 Medical device software -Software life-cycle processes • IEC/EN 62366-1 Medical devices - Application of usability engineering to medical devices	x	N/A
	Requirements for Non-LTA holders		
28	Name and address	X	X
29	Quality management system certificate and Good Distribution and Storage practice certificate or equivalent	X	X
30	A verification report signed by the bidders' authorized personnel and supporting documentation that established the compliance of the product submitted for the bidding and supplied to the user	x	N/A
31	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
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