Assessment of Medical Devices Team

Prequalification Unit – Regulation and Prequalification Department

POSITION NOTE

Medical device accessories supplied with WHO prequalified/EUL-listed IVDs

Summary

This position note clarifies WHO's expectations for medical device (MD) and in vitro diagnostic (IVD) accessories supplied with or recommended for use with WHO prequalified or emergency use listed (EUL-listed) IVDs.

- **WHO's prequalification listing and WHO's Emergency Use listing apply exclusively to the IVD subject to the prequalification decision and not to associated accessories.**
- **Regulatory Status of Accessories:**
  - Accessories that meet the definition of an IVD in their own right are considered regulated products and must comply with applicable requirements (refer to the definitions in Annex A).The legal manufacturer of a WHO prequalified IVD/EUL-listed remains responsible for selecting, qualifying, and monitoring accessory suppliers and for ensuring that evidence demonstrating conformity and appropriate labelling/information is available.
  - For Class A (Low-risk) accessories, a manufacturer's Declaration of Conformity supported by traceable technical documentation is generally acceptable (see Section 5).
  - For Class B and higher (Moderate/High risk) accessories, evidence of independent conformity assessment and/or regulatory authorization from a recognized regulatory authority or designated conformity assessment body is expected (see Section 6). Without such evidence, the accessory will not be considered acceptable for supply or recommended for use alongside a WHO prequalified/EUL-listed IVD (see Section 6).
  - For products already prequalified for which certain accessories do not yet meet these requirements, a transition period of 36 months from the effective date of this note is provided for the implementation of necessary action and bringing accessories to compliance (see Section 8).

1. Purpose

Following nonconformities identified during post-market surveillance (PMS) activities and during the review of accessories supplied with WHO prequalified/EUL-listed IVD medical devices, and in light of evolving global regulatory expectations, including the IMDRF Essential Principles of Safety and Performance, WHO's Prequalification of IVD team issues this position note to clarify expectations for MD and IVD accessories and to outline the evidence WHO expects to be available to support their conformity.

2. Background

WHO prequalified/EUL-listed IVDs may be supplied with, or recommended for use with, accessories (e.g., readers, measuring devices, specimen collection and sampling devices, including sterile lancets) that are necessary for safe and correct use in the intended use configuration.

Under internationally harmonized frameworks (GHTF/IMDRF) referenced by WHO, certain accessories are regulated products, in their own right (as medical devices, IVDs, or accessories of IVDs), depending on their intended purpose and status.

Definitions used in this note are provided in Annex A.

WHO prequalification or EUL listing applies only to the IVD subject to the prequalification decision and does not extend to associated accessories. WHO prequalification or EUL listing should therefore not be interpreted as WHO's recognition of the regulatory compliance of any accessory supplied with, or recommended for use with, a WHO prequalified/EUL-listed IVD.

3. Scope

This position note applies to all MD and IVD accessories supplied with, or recommended for use with, a WHO prequalified/EUL-listed IVD where the accessory is:

- included in the test kit, or supplied separately but recommended by the IVD manufacturer; and
- essential for operation, safe use, or correct performance of the IVD in its intended use configuration.

4. WHO position and general principles

WHO's expectations are as follows:

1. Accessories that meet the definition of a MD or IVD, or accessories that are subject to applicable regulatory requirements according to IMDRF/GHTF definitions, should meet the IMDRF Essential Principles of Safety and Performance:

Where applicable, accessories to the prequalified IVD are expected to conform to relevant standards/technical specifications appropriate for their intended purpose and risks (for example

electrical safety, electromagnetic compatibility (EMC), mechanical safety, chemical/biological safety (including biocompatibility), sterility or bioburden controls, usability and human factors, and environmental/transport robustness).

2. WHO prequalification or EUL listing of an IVD does not constitute WHO prequalification or EUL listing of any associated accessory:

The legal manufacturer of a WHO prequalified IVD remains responsible for ensuring that any accessory supplied with, or recommended for use with, the prequalified/EUL-listed IVD is appropriate for the intended use configuration and is supported by adequate evidence of conformity to applicable standards, including compliant labelling and information supplied by the manufacturer.
The manufacturer stays solely responsible for identifying any additional regulatory requirements that apply to the accessory beyond those assessed within the scope of WHO prequalification, and for maintaining ongoing compliance and control of associated risks.

3. The legal manufacturer of a WHO prequalified IVD must maintain traceable documentation demonstrating accessory conformity and make it available to WHO upon request (e.g., during assessments, inspections, change notifications, or PMS follow-up).

5. Evidence requirements for Class A IVD or MD accessories

Where an accessory to a prequalified IVD is classified as a Class A (low risk) MD or IVD under the applicable IMDRF/GHTF classification framework, a manufacturer's self-declaration of conformity, referencing a technical documentation, will be generally considered sufficient by WHO.

However, the documentation should be kept available under the manufacturer's Quality Management System (QMS) to demonstrate:

- the accessory's intended purpose and compatibility with the WHO prequalified IVD (intended use configuration);
- risk management and appropriate verification/validation, as applicable;

where applicable, evidence of conformity with relevant standards or equivalent methods, proportionate to risk (e.g., electrical safety/EMC for powered accessories; chemical/biological safety, etc.).

- labelling and instructions for use that support safe and correct use;
- change control, supplier qualification, and monitoring of ongoing conformity.

The legal manufacturer of a WHO prequalified IVD remains fully responsible for selection and qualification of Class A accessory suppliers and for verification of continued compliance with applicable requirements and the IMDRF Essential Principles.

6. Evidence requirements for Class B and higher IVD or MD accessories

For accessories classified as Class B or higher under IMDRF/GHTF's classification, WHO expects evidence of independent conformity assessment and/or regulatory authorization as a condition for accepting an IVD for supply or for recommending its use alongside a WHO prequalified IVD.

Minimum evidence expected to be available for WHO applications includes:

- documented evidence of conformity, as applicable (e.g., Declaration of Conformity, key test reports, and supporting technical documentation);
- a valid certificate, authorization, or attestation of conformity issued by a recognized regulatory authority (see definition in annex A below) or designated conformity assessment body demonstrating compliance with applicable IMDRF Essential Principles of safety and performance.

Without such independent conformity evidence, the accessory will not be considered acceptable for supply or recommended for use with a WHO prequalified IVD.

The WHO prequalified IVD legal manufacturer remains fully responsible for selection and qualification of Class B and higher accessory suppliers and for verifying and maintaining accessory compliance (including monitoring changes and management of post-market signals).

7. Conclusion

MD and IVD accessories supplied with, or recommended for use with, WHO prequalified IVDs must be treated as compliance bound medical devices or IVDs in accordance with the IMDRF regulatory framework, and may also be subject to additional applicable regulatory requirements, and must therefore demonstrate conformity with relevant obligations. For Class B and above (or equivalent), evidence of independent conformity assessment/regulatory authorization is mandatory, when those accessories are not themselves prequalified by WHO. This supports safety, performance, and regulatory compliance of the overall diagnostic solution.

Where IVDs are supplied with lancing devices (or similar accessories) that do not meet these expectations, manufacturers may be contacted to provide a corrective and preventive action (CAPA)/compliance action plan to describe how and when full conformity will be achieved.

8. Transition arrangements

The requirements outlined in this document apply to any new submission to prequalification or reportable change request application and specifically include sterile lancets provided with the kits.

A transition period of 36 months from the effective date of this position note is provided for products that are already prequalified or that do not undergo changes. During this period, manufacturers are invited to communicate and implement plans to meet these expectations. WHO may apply a risk-based approach during the transition period, including follow-up actions through PMS.

Manufacturers of products that are already prequalified are expected to assess whether the sterile lancets provided with their kits meet these requirements. If gaps are identified, manufacturers should submit the appropriate change request to WHO, including supporting evidence, to address the gaps.

During the transition period, manufacturers are expected to identify and close gaps in conformity with applicable and relevant standards/technical specifications, proportionate to risk, and to ensure that associated evidence remains current and traceable for the kits and any sterile lancets included with them.

Annex A. Definitions and key references (informative)

A. Definitions and key IMDRF / GHTF references (informative)

a. Harmonized definitions (GHTF/SG1/N071:2012)

i. Medical device (MD)
A "medical device" is any instrument, apparatus, implement, machine, appliance, implant, reagent for in vitro use, software, material or other similar or related article intended by the manufacturer to be used for specific medical purposes (e.g., diagnosis, prevention, monitoring, treatment), and which does not achieve its primary intended action by pharmacological, immunological, or metabolic means (though it may be assisted by such means).
Source: GHTF/SG1/N071:2012, Section 5.1. [Available at GHTF SG1 Definition of the Terms 'Medical Device' and 'In Vitro Diagnostics' Medical Device's] imdrf.org

ii. In vitro diagnostic (IVD) medical device
An "IVD medical device" is a medical device intended for the in vitro examination of specimens derived from the human body, solely or principally to provide information for diagnostic, monitoring, or compatibility purposes. IVDs include, for example, reagents, calibrators, control materials, specimen receptacles, software, and related instruments.
Source: GHTF/SG1/N071:2012, Section 5.2. [Available at GHTF SG1 Definition of the Terms 'Medical Device' and 'In Vitro Diagnostics' Medical Device's] imdrf.org

iii. Accessory to a medical device / accessory to an IVD medical device
An accessory is an article intended specifically by its manufacturer to be used together with a particular MD (or IVD) to enable or assist that device to be used in accordance with its intended use.
Source: GHTF/SG1/N071:2012, Section 4.0 (ancillary definitions). [Available at GHTF SG1 Definition of the Terms 'Medical Device' and 'In Vitro Diagnostics' Medical Device's] imdrf.org

Note for users of this document: Some jurisdictions include accessories within the definition of MD/IVD; others regulate accessories separately while still applying appropriate controls (e.g., classification, conformity assessment). [Available at GHTF SG1 Definition of the Terms 'Medical Device' and 'In Vitro Diagnostics' Medical Device's] imdrf.org

b. Key IMDRF references (current editions)

iv. Essential Principles of Safety and Performance
IMDRF/GRRP WG/N47 FINAL:2024 (Edition 2) describes globally harmonized Essential Principles intended to help ensure devices are safe and perform as intended. [Available at IMDRF GRRP WG N47 (Edition 2).pdf] imdrf.org+1

v. Labelling and information supplied by the manufacturer
IMDRF/GRRP WG/N52 FINAL:2024 (Edition 2) provides globally harmonized principles for device labelling, supporting implementation of the Essential Principles. [Available at IMDRF GRRP WG N52 (Edition 2).pdf] imdrf.org+1

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c. Recognized authorities for WHO abridged assessment

vi. Recognized Regulatory Authority (RRA) for the purposes of WHO's abridged prequalification assessment of IVDs
For the purpose of WHO's abridged prequalification assessment, WHO may rely on evidence that the regulatory version of a product has been **stringently assessed and approved** by a **Recognized Regulatory Authority (RRA)**, as described in WHO PQDx_173 (Abridged PQ assessment). RRAs and eligibility conditions are defined within that procedure and may be updated over time. [Available at PQDx 173 Abridged PQ assessment_0.pdf] extranet.who.int

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d. Applicable standards and technical specifications (general)

vii. Conformity to applicable standards (risk-based)
Where relevant, conformity evidence should also address applicable and relevant **standards/technical specifications** proportionate to the accessory's technology and risk (e.g., electrical safety and electromagnetic compatibility for powered devices; mechanical safety; chemical/biological safety including biocompatibility; sterility/bioburden controls where applicable; usability/human factors; environmental/transport robustness), or include a documented justification for equivalent methods.