

WHO Prequalification of medical devices FAQs

Programme Scope & Eligibility

Q: How is eligibility for WHO Prequalification determined, and why are certain products included while others are not?

A: The scope of WHO Prequalification is determined in collaboration with WHO technical programmes and is driven by public health priorities and programmatic needs. Technical programmes identify priority products and areas where quality-assured products are needed. Some product categories are newly included, while others have been incorporated from existing quality assurance activities to bring them under the broader WHO Prequalification framework. The list of products currently eligible for assessment are published [here](#)

Q: Are there plans to expand the WHO Prequalification scope to include additional medical device categories?

A: At present, there are no specific plans to expand the WHO Prequalification scope to additional medical device categories. However, there is interest in certain product areas, and any future decisions on scope expansion will be communicated to stakeholders in advance.

Q: My company is familiar with WHO PQ for IVDs. What are the main differences for medical devices?

A: The overall WHO PQ approach for medical devices is largely the same as that used for IVDs. The core assessment framework, processes, and principles remain unchanged. The main difference is that no separate WHO performance evaluation is required as a prerequisite to prequalification assessment of MDs, and the product dossier requirements and technical assessment are tailored to the specific characteristics of medical devices.

Regulatory Framework & National Registration

Q: Does WHO Prequalification, CE marking, or FDA authorization replace national regulatory approval requirements?

A: No. WHO Prequalification, CE marking, or FDA authorization do not replace national regulatory requirements. The national authority remains responsible for the final regulatory decision. Manufacturers must continue to comply with applicable registration, licensing, and market authorization requirements in each country.

Q: How does WHO support national registration of prequalified medical devices?

A: WHO PQ can significantly facilitate national registration of a prequalified medical device by providing regulators with an independent, standardized assessment of the product's quality, safety, and performance, the results of which are published on the WHO website, including in a public report (WHOPAR and WHOPIR).

Q: Will there be a Collaborative Registration Procedure (CRP) available for medical devices that receive PQ through this new process?

A: Currently, the CRP is not established for medical devices. WHO will explore opportunities to extend such approaches to medical devices in the future.

Application & Assessment

Q: Is it mandatory for a manufacturer to have EU MDR certification to apply for WHO Prequalification?

A: No. EU MDR certification is not required. Manufacturers must demonstrate compliance with prequalification requirements, no other regulatory approval is mandatory.

Q: Can a Class IIb medical device with a CE mark under the MDD or MDR be eligible for the WHO PQ abridged assessment procedure?

A: Yes. Class IIb devices assessed by a Notified Body under MDR only may be eligible for abridged assessment, subject to WHO eligibility criteria. The acceptable stringent assessments by recognized regulatory authorities are available [here](#).

This FAQ is intended to provide clarification and practical guidance. It does not establish requirements. Requirements are defined in the relevant approved policies, procedures, and guidance documents available on the WHO PQ website

Q: What is the average timeline and cost structure for the WHO Prequalification process, from application submission to final listing?

A: WHO target timelines are published [here](#). Overall timelines (WHO and manufacturer time) depend on the quality and completeness of the submission and manufacturer responsiveness. Information on fees are available [here](#) and in WHO PQ [guidance](#).

Inspections

Q: Why would a manufacturer need to undergo a WHO PQ inspection if it is already certified under MDSAP?

A: WHO uses a risk-based approach. Existing certifications such as MDSAP may be leveraged, but additional evidence or an on-site or desktop inspection may be needed where WHO-specific requirements have not been assessed.

Q: Is an on-site inspection mandatory for CAD-TB products?

A: Not necessarily. WHO determines inspection requirements through a risk-based assessment of the product, manufacturing activities, and available evidence.

Q: When WHO PQ invites NRA observers to participate in an inspection, are they from the local country or another country?

A: NRA observers are from the local regulatory authority of the country where the inspection takes place.

Q: Is site inspection required for an abridged assessment?

A: Yes. An abridged assessment includes three components:

- Review of an abridged product dossier
- Manufacturing site inspection
- Labelling review

Therefore, a manufacturing site inspection remains part of the abridged assessment process.

This FAQ is intended to provide clarification and practical guidance. It does not establish requirements. Requirements are defined in the relevant approved policies, procedures, and guidance documents available on the WHO PQ website

Q: Is the WHO inspection services compliant with ISO 17021?

A: WHO PQ is not certified to ISO 17021 because it is not a certification body. However, its quality management system incorporates many principles consistent with internationally recognized inspection and quality assurance practices.

Post-Prequalification / Lifecycle Management

Q: What changes need to be reported to WHO after a product has been prequalified?

A: WHO provides dedicated [guidance](#) describing which changes are reportable and which do not require notification. Manufacturers are not expected to report every change.

Q: How are timelines handled for changes that were previously submitted to UNFPA?

A: WHO PQ timelines apply only to submissions made under WHO PQ. Changes submitted to WHO PQ are screened within 30 days, with review timelines depending on complexity and completeness, as defined in the dedicated guidance document.

Q: What is the frequency of reassessment for a prequalified product?

A: WHO does not require periodic requalification. Instead, it follows a lifecycle approach based on change management, post-market oversight, and continued compliance with PQ requirements, including post-listing obligations.

Q: How should a WHO Notice of Concern be interpreted, particularly if the product also holds other regulatory approvals such as a CE mark?

A: A Notice of Concern indicates that WHO has identified significant concerns regarding a product. Stakeholders should consider the notice alongside information from other regulatory authorities when making risk-based decisions.

Transition from UNFPA

Q: Does a UNFPA prequalified manufacturer need to be re-registered under the WHO Prequalification Programme?

A: Yes. In order to be acknowledged as UNFPA listed on the WHO prequalification website, manufacturers currently listed under the UNFPA programme will need to agree to the conditions outlined in the WHO letter of agreement and submit an application in accordance with WHO transition arrangements and timelines.

Transparency & Procurement

Q: What information about prequalified products will be publicly available to support procurement and verification activities?

A: WHO will publish key product details through its list of prequalified products, including manufacturer information, site address, product identification details, and also published public assessment and inspection reports (WHOPARs and WHOPIRs) with a summary of the assessment.