Launch of WHO’s Prequalification of Medical Devices

On 25 September 2026, the World Health Organization (WHO) has officially launched prequalification (PQ) assessments for medical devices, expanding the portfolio of health products covered by WHO prequalification and reinforcing access to safe, quality-assured and effective health technologies worldwide.

The launch marks an important milestone in WHO's efforts to strengthen global health systems and support evidence-based procurement decisions by United Nations agencies, international organizations and Member States. Through a standardized and transparent assessment process, WHO prequalification helps ensure that priority health products meet internationally recognized requirements for quality, safety and performance/efficacy, while remaining suitable for use in resource-limited settings.

Initial Scope of prequalification assessments

The first category of products eligible for assessment under WHO’s prequalification includes:

- Male latex condoms;
- Female condoms;
- Intrauterine devices (IUDs);
- Computer-aided detection software for tuberculosis screening (CAD-TB); and
- Male circumcision devices (which were previously assessed under a separate process).

WHO anticipates that the scope of eligible medical devices will expand progressively in line with public health priorities and programme capacity.

A Harmonized Framework for Contraceptive Devices

The launch of WHO’s prequalification assessments also marks the transition of contraceptive device assessments previously conducted by the United Nations Population Fund (UNFPA) to WHO.

This transition consolidates responsibility for the assessment of priority health products within WHO's Prequalification Team, promoting greater consistency, coherence and efficiency across prequalification activities. Contraceptive devices will now be assessed under a framework aligned with established WHO prequalification approaches, including those used for in vitro diagnostics (IVDs), while incorporating internationally recognized standards, regulatory guidance and structured dossier requirements.

The new framework further strengthens regulatory convergence through the use of reliance principles, enabling WHO to consider regulatory decisions issued by national regulatory authorities that apply comparable assessment approaches. It also introduces enhanced lifecycle management mechanisms, including systematic post-qualification monitoring and timely reporting of product changes.

Supporting Innovation for Tuberculosis Screening

The inclusion of CAD-TB products reflects WHO's commitment to improving access to innovative technologies that can support the early detection of tuberculosis and advance equitable access to diagnostics.

This work builds upon WHO recommendations and policy guidance on the use of computer-aided detection software for TB screening and aims to facilitate the availability of quality-assured digital health technologies in countries with a high burden of tuberculosis.

Integration of Male Circumcision Devices

Male circumcision devices have been included within WHO PQ's scope of work for several years. Their integration into the broader medical devices prequalification framework creates a more consistent approach to evaluation, oversight and lifecycle management across product categories, while maintaining the high standards already established for these devices.

WHO's Prequalification of Medical Devices

WHO's prequalification of medical devices is a comprehensive assessment process applied to individual products through a standardized procedure designed to determine whether a product satisfies WHO's requirements for quality, safety and performance.

Particular emphasis is placed on products that address major public health priorities and are appropriate for deployment in resource-limited settings. The prequalification procedure includes assessment of product documentation, evaluation of supporting evidence, review of manufacturing quality management systems and ongoing post-qualification oversight.

Products that successfully complete the assessment process are included in WHO's List of Prequalified Medical Devices.

The outcomes of WHO PQTs assessments serve as an important resource for UN agencies, international procurement organizations, donors and national authorities when making purchasing and policy decisions. Continued prequalification status remains contingent upon manufacturers fulfilling all applicable post-qualification obligations and maintaining compliance throughout the product lifecycle.

Transitional Arrangements for UNFPA-Listed Contraceptive Devices

To facilitate the transition of contraceptive device prequalification activities from UNFPA to WHO, WHO will acknowledge contraceptive devices currently included in the UNFPA prequalification lists for a transitional period ending on 30 September 2030, subject to the manufacturer's acceptance of, and compliance with, the applicable WHO requirements.

Manufacturers of products acknowledged under this transitional arrangement must:

- Sign and comply with the applicable WHO Letter of Agreement and all relevant provisions of the WHO Prequalification Procedure for Medical Devices;
- Comply with all WHO post-qualification obligations and requirements throughout the transition period;
- Submit a new application for WHO prequalification assessment no later than 30 September 2028;
- Notify WHO, in accordance with WHO change reporting requirements, of any planned or implemented reportable changes to the product.

Products for which a new WHO prequalification application is not submitted by 30 September 2028 will no longer be acknowledged by WHO and will be removed from the WHO webpage acknowledging UNFPA-listed contraceptive devices.

Applications Previously Submitted to UNFPA

Applications previously submitted under the UNFPA contraceptive device assessment procedure that have not resulted in a UNFPA listing must be submitted to WHO in accordance with the WHO Prequalification Procedure for Medical Devices.

For products for which the applicable UNFPA assessment fee has already been fully paid, WHO will waive the corresponding WHO prequalification assessment fee. These products will receive priority consideration during the initial assessment wave.

- Products previously submitted to the UNFPA, together with CAD-TB products and male circumcision devices, will be eligible for WHO assessment beginning 1 October 2026.
- Contraceptive devices not previously submitted to and accepted by UNFPA will be eligible for WHO assessment beginning 1 April 2027.
- Applications for changes to contraceptive devices currently listed by UNFPA may be submitted to WHO from 1 October 2026 onward.

Key Dates

Date	*Milestone*
25 September 2026	Official launch of WHO's Prequalification of Medical Devices
1 October 2026	Opening of first assessment wave for products previously submitted to the UNFPA, CAD-TB products and male circumcision devices; and Acceptance of change applications for currently UNFPA-listed contraceptive devices
1 April 2027	Opening of applications for contraceptive devices not previously submitted to the UNFPA
30 September 2028	Deadline for currently UNFPA-listed contraceptive devices to submit a WHO prequalification application
30 September 2030	End of WHO's acknowledgement of UNFPA-listed contraceptive devices during the transition period

Information for Applicants

WHO has published the medical devices prequalification procedure, application forms, guidance documents and supporting instructions to assist applicants in preparing submissions.

Medical Devices | WHO - Prequalification of Medical Products (IVDs, Medicines, Vaccines and Immunization Devices, Vector Control)

Manufacturers intending to submit products for WHO prequalification are encouraged to notify WHO in advance by completing and returning the **Intention to Submit Form** to:

diagnostics@who.int

Advance notification will assist WHO in planning assessment activities, allocating resources and facilitating communication with applicants regarding anticipated submission timelines.

Intention to submit form for prequalification assessment

Manufacturer information

Name of legal manufacturer		
Legal manufacturer address		
Authorized contact name(s)		
Authorized contact email address(es)		
Do you plan to submit to WHO's prequalification assessment	☐Yes Planned date of submission:	☐No

Product - Information

Tick the applicable device from the options below:

☐ Male latex condom ☐ Female condom ☐ IUD

☐ Male circumcision device ☐ CAD TB software

Product name(s)	
Product code(s)	
If multiple product codes exist, please provide a description of configurations (e.g. variants, accessories, pack sizes etc.) associated with the product code	
Name of jurisdiction where product is registered and commercialized	Type of regulatory status/approval

History of product assessment by UNFPA (contraceptive devices only)

Is your product already included on the UNFPA prequalified list of contraceptives	☐Yes Date of listing:	☐No
Has UNFPA previously accepted your application for assessment	☐Yes	☐No
If **yes**, please provide the date of the submission	Click or tap to enter a date.	
UNFPA assessment status	☐ Application submitted/ Under assessment ☐Prequalified by UNFPA ☐ Other: _____	