Eligibility criteria for WHO's prequalification assessment of medical devices

Suggested citation. Eligibility criteria for WHO's prequalification assessment of medical devices. Geneva: World Health Organization; 2026. https://doi.org/10.2471/B09643.
Licence: CC BY-NC-SA 3.0 IGO.
Cataloguing-in-Publication (CIP) data. CIP data are available at https://iris.who.int/.
Sales, rights and licensing. To purchase WHO publications, see https://www.who.int/publications/book-orders. To submit requests for commercial use and queries on rights and licensing, see https://www.who.int/copyright.

1. Introduction

This document has been prepared by WHO to provide information on the eligibility principles and eligibility criteria applicable for medical device to undergo WHO's prequalification assessment pursuant to document PQDx_464 *"WHO's prequalification procedure for medical devices*".

To be eligible to apply for and undergo WHO's prequalification assessment, the relevant product must, among other things, meet the eligibility principles and eligibility criteria established by WHO, as further described in this document. Manufacturers wishing to apply for WHO's prequalification assessment of their product(s) should read this document before doing so.

Note that in vitro diagnostic (IVD) medical devices are not covered in the scope of this document.

2. Eligibility for WHO's prequalification assessment of IVDs

2.1. Eligibility principles

To facilitate meeting the needs of WHO Member States and UN agencies, the scope of WHO's prequalification assessment is defined by WHO according to the following eligibility principles:

- The need for a product for a particular disease or disease state; and
- The appropriateness of the product for use in resource-limited settings; and
- The requests from WHO Member States for particular products; and
- The products of interest to UN organizations and other procurement agencies; and
- The existing or planned recommendation in WHO disease specific testing guidelines.

Applications for WHO's prequalification assessment of medical devices are accepted only for products that are found by WHO to meet the eligibility principles set forth in this document.

2.2. Eligibility criteria

Applications for WHO's prequalification assessment are only accepted for products that are found by WHO to meet the below eligibility criteria:[1]

- Applications for WHO's prequalification assessment may only be submitted by the original manufacturer of the product.[2] WHO will not accept applications submitted by rebranders or applications of rebranded products.
- Without prejudice to the other eligibility criteria, applications for WHO's prequalification assessment of IVDs are only accepted for products that have final design lock down at the time such application is submitted to WHO. [3] Any

[1] WHO reserves the right to apply other criteria dependent on changing global health needs, the particular needs of WHO Member States, and the emergence of new and relevant technologies.

[2] The definitions of a "manufacturer", "rebrander" and "rebranded product" are found in document PQDx_464 "*WHO's prequalification procedure for medical devices".*

[3] The definition of "design lockdown" is provided in document PQDx_464 "*WHO's prequalification procedure for medical devices".*

exemptions must be agreed upon by WHO in writing prior to the submission of the application for prequalification.

The eligibility criteria may be reviewed and amended by WHO, following internal consultation with WHO programmes.

3. Lists of products eligible for WHO's prequalification assessment

Subject to the terms and conditions of WHO's prequalification procedure for medical devices and to the aforementioned eligibility principles and eligibility criteria, the types of medical devices that WHO currently accepts for WHO's prequalification assessment are listed on WHO's website https://extranet.who.int/prequal/medical-devices/medical-devices-eligible-prequalification. WHO reserves the right to review and amend, from time to time, the products listed therein.

4. Assessment of eligibility and communication of outcome

Once the manufacturer has submitted to WHO the complete pre-submission form and required attachments, WHO will review them against the aforementioned eligibility principles and criteria. Thereafter, WHO will determine and inform the manufacturer in writing:

- whether or not the application is accepted (i.e., whether or not product is eligible for WHO's prequalification assessment); and
- assuming the application is accepted, the next steps to be followed depending on the prequalification assessment pathway (full or abridged) applicable to the product.

If the application is accepted (i.e., if the product is found by WHO to be eligible for WHO's prequalification assessment), then WHO will also request the manufacturer to, among other things: (a) complete, sign and return to WHO a Letter of Agreement for WHO's prequalification assessment of the product, using the document provided by WHO for this purpose, as well as (b) pay WHO's prequalification fees.

Before WHO's prequalification assessment of a product may commence and proceed, the manufacturer must first ensure that it has fully met the conditions mentioned in clauses (i), (ii) and (iii) of Section 6.3 of the WHO document PQDx_464 "WHO's prequalification procedure for medical devices".

If WHO finds that the product is not eligible for WHO's prequalification assessment, then the application will be rejected, and the product will not be accepted for or undergo WHO's prequalification assessment.

5. Relevant documents

The following WHO documents and webpages, among others, provide information to guide the manufacturer through the requirements of WHO's prequalification assessment:

- https://extranet.who.int/prequal/medical-devices
- WHO's prequalification procedure for medical devices. Geneva: World Health Organization (PQDx_464)
- Pre-submission form for WHO's prequalification assessment of medical devices. Geneva: World Health Organization (PQDx_466)

- Instructions for completion of the pre-submission form for WHO's prequalification assessment of medical devices. Geneva: World Health Organization (PQDx_467)

6. Contact information

Any inquiries regarding WHO's prequalification assessment of medical devices should be addressed to: diagnostics@who.int