



**Instructions for completion of the
pre-submission form for WHO's
prequalification assessment of medical
devices**

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Introduction

Manufacturers wishing to apply for WHO's prequalification assessment of a medical device are required to complete and submit to WHO a pre-submission form using the form found in document PQDx_466 *"Pre-submission form for WHO's prequalification assessment of medical devices"*, together with the necessary supporting documentation and attachments.

This document has been prepared to assist manufacturers in correctly completing and submitting the pre-submission form, together with the necessary supporting documentation and attachments. The information provided by the manufacturer in pre-submission form assists WHO to determine:

- a. whether or not the product submitted is eligible for WHO's prequalification assessment; and
- b. if the product submitted is eligible for WHO's prequalification assessment, whether or not WHO's prequalification assessment can be abridged; and
- c. the regulatory version that is accepted by WHO for WHO's prequalification assessment; and
- d. the planning of each of the components of WHO's prequalification assessment.

Therefore, the manufacturer must fill out the pre-submission form with accuracy and completeness.

Manufacturers applying for WHO prequalification assessment of medical devices should read the instructions in this document and the medical device pre-submission form before completing the medical device pre-submission form. In addition, manufacturers should read the document PQDx_464 *"WHO's prequalification procedure for medical devices"* before applying, so that they can be aware of and prepared for all stages of WHO's prequalification assessment process.

Submitting the pre-submission form

Once the manufacturer has duly and fully completed, signed and dated the pre-submission form, that form and its attachments (e.g. ePQS new user registration form, official letter regarding the manufacturer's authorized contacts, instructions for use of the product in English, summary of clinical evidence if applicable, etc.) are required to be submitted following the instructions in the pre-submission form.

Electronic copy requirements

- The primary file format used for documents submitted to WHO should be Portable Document Format (PDF). The manufacturer must not include any PDF in the electronic submission that requires a password to open it.
- The document must be compatible with optical character recognition programs (OCR). For any scanned document, OCR must be used to allow text to be searchable. This can be verified by: (1) highlighting an area of text and (2) using the software search function to locate a particular word or phrase. If the word or phrase is not returned in the search, then the OCR did not recognize the text and it is, therefore, not searchable.
- The pre-submission form and required attachments must be submitted as separate files named as "Pre-submission [product name]", "ePQS new user registration form", "Authorization letter", "Instruction for Use [IFU code or reference]", "Clinical evaluation report summary". Keep the name of the annexes as short and practicable as possible avoiding special characters such as slashes, quotation marks, asterisks, mathematical or non-ASCII symbols) as they are not compatible with WHO's storage platform.

- The path length for each document submitted, including any folders and the file name itself, must not exceed 120 characters.
- When completing the pre-submission form, the manufacturer must use font sizes of a style and size large enough to be easily legible. Fonts smaller than 12 points must be avoided except in tables and footnotes where a font size of 10 points is acceptable.
- When creating a PDF from an electronic source document (e.g. Microsoft Word document) the manufacturer must avoid using specialist application plug-ins for capture or display data as not all reviewers of the documentation will necessarily have access to these plug-ins.

If necessary, WHO may request the manufacturer to provide additional information and/or clarifications, including to assist WHO in its eligibility decision. The manufacturer must provide WHO with the information and/or clarifications requested within the deadlines determined by WHO. The manufacturer will be provided with two opportunities to correctly complete the pre-submission forms with all requested information. If the manufacturer fails or delays to provide the necessary information after those two opportunities, the application will be rejected, and the product will not undergo WHO's prequalification assessment.

NOTE: Manufacturers must not submit a product dossier along with the pre-submission form. Product dossiers that are submitted without a formal request from WHO will be destroyed.

The numbering of the following sections corresponds and refers to those sections in the pre-submission form. The manufacturer must not modify the descriptions in the pre-submission form tables.

1. Manufacturer information

1.1. Legal manufacturer

Please provide all information required under this section about the manufacturer of the product in question.

For the purpose of WHO's prequalification, WHO uses the following definition of "manufacturer"¹.

"Manufacturer" means any natural or legal person with responsibility for design and/or manufacture of a medical device with the intention of making the medical device available for use, under his or her name, whether or not such a medical device is designed and/or manufactured by that person him- or herself or on his or her behalf by (an)other person(s).

Applications for WHO's prequalification assessment of medical devices must only be submitted by the original manufacturer of the product.

1.2. Authorized contacts for the manufacturer

Please insert all the information required under this section regarding each of the two authorized contacts for the manufacturer. The "authorized contacts for the manufacturer" are two officers, employees or representatives of the manufacturer who are duly and fully authorized and designated to act in the name and on behalf of the manufacturer in all respects and for all purposes in connection with WHO's prequalification assessment of the medical device in question.

These two authorized contacts will be the primary contact points for WHO in relation to WHO's prequalification assessment for the medical device for which the pre-submission form is

¹From document PQDx_464 "WHO's prequalification procedure for medical devices".
PQDx_467 Version2

submitted. Therefore, the manufacturer must ensure that all contact details provided in the pre-submission form are current, complete and correct.

In connection with this section, the manufacturer must also submit to WHO an official letter, signed by a duly authorized representative of the manufacturer, stating that the persons listed as “authorized contacts” in section 1.2 of the pre-submission form (which persons must also be named in that letter) are duly and fully authorized/designated to act in the name and on behalf of the manufacturer in all respects and for all purposes in connection with the WHO’s prequalification assessment of the product in question (which product must also be identified in that letter).

This letter must be submitted to WHO together with the duly completed pre-submission form.

In the event that, at any time during WHO’s prequalification assessment process, there is a change in the name(s) and/or contact information of any authorized contact(s), the manufacturer must promptly notify WHO, in writing, thereof and of the updated name(s) and contact information of the authorized contacts. Such notice must be given by official letter as described above, sent to WHO by email to diagnostics@who.int.

2. Product – Information

2.1. Product name, product code, catalogue number for WHO’s prequalification assessment²

2.1.1. Only one medical device is permitted per pre-submission form. Provide the name for one product only.

2.1.2. Provide the product code/catalogue number for the product.

2.1.3. For each product code, complete a column in the table with a description of the device configuration/variants for example the product size, contents of kit, the quantity/units/volume of all accessories.

- Any placement, removal or other accessories provided with the device should be described.

2.1.4. Provide the date of design lock-down for the product (for new devices).

Applications are only accepted for products that have final design lock down at the time the medical device pre-submission form for WHO’s prequalification assessment is received by WHO.

For purposes of WHO’s prequalification assessment, the term “**design lock-down**” relates to a formal milestone in the IVD, medical device, or system development lifecycle at which the design is considered finalized: all design inputs have been addressed, and verification and validation activities are complete (note 1). The design is placed under configuration control and formally released for manufacturing, regulatory submission, or subsequent development stages. From this point forward, any modifications are strictly managed through a documented design change control process, including risk management review, necessary validation and verification and—where applicable—regulatory notification or approval, in order to maintain a stable and traceable design baseline.

Note 1: Verification and validation refer here to activities necessary to demonstrate that the finalized design meets the specified requirements defined in design inputs, intended use and applicable safety and performance requirements. These activities have been satisfactorily completed in accordance with the manufacturer’s quality management system and risk management process, and the design can be therefore considered a stable design baseline.

² WHO must be notified of all changes made to the product, as per document PQDx_464 *WHO’s prequalification procedure for medical devices*.

Note 2: Changes that occur after a design lock-down must be documented and evaluated within the framework of change management and risk management procedures.

2.2. Current instructions for use and user manual

Provide document control details for the instructions for use and the user manual(s) relevant to the product, including the IFU and user manual's version number and issue/release dates. List all languages in which the IFU is currently available. Attach a copy of the English language version of the instructions for use (package insert) for the product.

The version of the instructions for use submitted with the medical device pre-submission form will be considered the official version submitted for WHO's prequalification assessment. During the course of WHO's prequalification assessment, the manufacturer cannot make changes to this version of the instructions for use without prior written notice to and agreement from WHO. Any changes to such instructions for use version that was submitted with the medical device pre-submission form must be agreed with WHO prior to their implementation or the prequalification assessment will be terminated.

2.3. Transport, storage and operating temperatures and shelf life

2.3.1. The transport, storage and operating conditions for all components must be clearly specified by the manufacturer for the product, including the relevant environmental parameters (e.g. temperature, humidity ranges, etc.) as indicated in the product labelling or instructions for use.

The manufacturer shall also provide the shelf-life upon manufacture or expected lifetime/service lifetime, as claimed on the product packaging (expiry date) and the instructions for use where applicable.

"Shelf-life upon manufacture" is the period of time from when the product is released for supply until the expiry date - during which the product performance is assured by the manufacturer while handled and stored under defined conditions.

"Expected lifetime/service lifetime" is the period of time the device is anticipated to safely meet its intended purpose.

2.3.2. Describe any additional storage conditions applicable to the product, if relevant.

Note that if the product is accepted for WHO's prequalification assessment, the manufacturer will be required to provide, as part of its product dossier submission, evidence (such as data generated through stability studies) demonstrating that the product continues to perform within specifications for the claimed shelf life.

3. Product - Intended Use

3.1. Intended use and clinical application

The intended use statement (as per the IMDRF Non-In Vitro Diagnostic Device Regulatory Submission Table of Contents) should clearly describe the:

- medical purpose of the device (what is the expected use, which results are expected)
- medical indication(s) for which the device is intended (e.g. diagnosis, monitoring, treatment, rehabilitation, or prevention)
- anatomical site(s) of use where applicable
- clinical use environment where device is intended to be used (e.g. home use, hospitals, laboratories). Multiple options can be indicated.
- intended use of the device (e.g. disease or medical condition that the device will diagnose, monitor, treat, prevent, mitigate or cure, parameters to be monitored)

- intended patient population including if applicable information about patient selection criteria (e.g. adults, paediatrics)
- intended user and the skills knowledge/training required to operate or use the device (e.g. healthcare professional or lay user)
- contraindications and/or limitations of use if applicable (e.g. disease or medical conditions)

4. Product – Device description and principle of operation

Please provide all information required under this section regarding the device description, mode of action, system configuration and operating characteristics. Tick the checkboxes where applicable.

4.1. Device description

Manufacturers should provide a brief description of the device and its key functional components including the device type (e.g. active, non-active, software-based). If the device includes any software components or AI-based elements, include a brief description of key functional components and technological characteristics. This information should be sufficient to understand the nature of the device and its risk classification.

4.2. Mode of action

A concise description of the mode of action should be provided and whether the device acts through mechanical, physical, electrical, thermal, radiation, software-driven, algorithm driven or other technological means. Where applicable, manufacturers should describe the involvement of software and/or artificial intelligence components, including their role in the functioning of the device. The description should be sufficiently detailed to allow the WHO to understand how the device functions, how it interacts with the human body or user.

4.3. Operational characteristics and use

Manufacturers should briefly describe the operational characteristics of the device and how it is intended to be used under normal conditions. This should include a brief description of the operational steps involved in using the device, from preparation through completion of the test or procedure. Manufacturers should indicate whether installation or set-up is required prior to operation and specify whether calibration is required. The description should explain briefly (no more than 50 words) the level and type of user interaction required during operation.

Manufacturers should also indicate the intended frequency of use of the device (e.g. continuous use, intermittent use, single use per patient, repeated use per day).

4.4. System configuration and compatibility with other medical devices, equipment and/or software

Where the device forms part of a system configuration or is intended to be used with other medical devices, equipment, or software, provide the required information in this field.

4.5. Indicative cost

Please provide the approximate unit cost per device in US Dollars or indicate “NA” where not applicable. Where applicable, costs of associated dedicated equipment, instrumentation, consumables, or accessories required for its intended use should be provided. Costs should be indicated in the case of leasing, renting, subscription model for SaMD, managed service agreement, pay per use model if applicable.

5. Product – Performance characteristics

Please provide all information required under this section regarding the validated performance characteristics of the medical device, as applicable to its intended purpose.

Performance characteristics should demonstrate that the device performs consistently, safely, and as intended under the recommended conditions of use, and should be supported by appropriate verification and validation data.

5.1. Performance characteristics

Where applicable, performance characteristics may include, but are not limited to:

- Key functional performance characteristics (e.g. accuracy, precision, repeatability, measurement ranges)
- Technical specifications
- Environment/operating ranges or limits (e.g. temperature, humidity conditions, power requirements)
- Reliability/durability characteristics (e.g. related to mechanical or physical performance such as strength, stability, wear resistance, or electrical or software performance related to fault handling, interoperability)
- Software or system performance characteristics (where applicable)
- Any other relevant performance characteristics applicable to the device

Only performance characteristics relevant to the device type, technology, and intended use should be provided. Sections or parameters that are not applicable to the device should be clearly identified as “NA” or “not applicable”.

Performance data shall be derived from appropriate bench testing, simulated-use testing, or clinical evidence, as applicable, and should be consistent with the information provided elsewhere in the technical documentation.

5.2. Clinical evidence

Indicate whether clinical investigations have been conducted by the manufacturer. Where applicable, a summary clinical evaluation report (maximum one page) supporting the manufacturer’s claims should be provided as an attachment.

For male circumcision devices, indicate if the device meets the requirements in the WHO Framework for clinical evaluation of devices for male circumcision. A summary clinical evaluation report is not required as an attachment.

6. Regulatory and commercial status of the product

6.1. Regulatory status of the product

Please provide all information required under this section regarding the regulatory status of the product being submitted for WHO’s prequalification assessment.

A “**regulatory version**” relates to all the information and documentation associated with a submission for approval of a product by a regulatory authority including, without limitation, all documentation related to development, manufacture, intended use, labelling and post-market surveillance of the product in question, as well as all documented evidence supporting the safety and performance claims associated with that submission. In the event that (i) regulatory versions of a product have been submitted to different regulatory authorities or assessment bodies (e.g., United States Food and Drug Administration, Health Canada, a Notified Body for CE marking, etc.) and (ii) any aspect of the documentation or information associated with such submitted regulatory

versions differs in any way, then the submitted regulatory versions are considered to be a *different* regulatory version.

6.1.1. Please identify the regulatory version of the product submitted for WHO's prequalification assessment (or planned regulatory version if the product is not yet commercially available).

6.1.2. Please tick/check the boxes that are relevant to your product and provide details of all current regulatory approvals for this product.

"National Regulatory Authority" means a government body or other entity that exercises a legal right to control the use or sale of medical devices within its jurisdiction and may take enforcement action to ensure that in vitro diagnostics marketed within its jurisdiction comply with legal requirements.

"Regulatory Approval" means that the National Regulatory Authority officially permits supply of this in vitro diagnostic product in the country/region under its authority.

"Type of Regulatory Approval" refers to the relevant sections of the legislation that have been applied to the product for regulatory approval. Generally, the details of the legislation applied for regulatory approval should be included on the certificate that demonstrates that the product is approved for supply.

6.2. Commercial agreements and re-branding

Please provide all information required under this section regarding rebranding of the product, or whether the product or any of the major components thereof sourced from another manufacturer. WHO requires that this commercial agreement information be made available to WHO in order to determine whether or not a product is eligible for WHO's prequalification assessment. Applications for WHO's prequalification assessment of medical devices are accepted only from the original manufacturer of the product.

6.3. History of product assessment by WHO or UNFPA

Provide information required under this section on any previous WHO assessments or UNFPA (United Nations Population Fund) assessments (in the case of contraceptive devices) of the product.

7. Manufacturer – Quality management system

An effective quality management system is a key consideration for all manufacturers of medical devices. Therefore, products submitted for WHO's prequalification assessment must be manufactured under an appropriate quality management system.

The quality management standard "ISO 13485 Medical devices — Quality management systems — Requirements for regulatory purposes" is considered to be a benchmark in quality management for the manufacturers of medical devices by regulatory agencies throughout the world. WHO's prequalification assessment (including its manufacturing site inspections) is based on the requirements of this internationally recognized quality management standard.

Provide all information required under this section about the manufacturer's quality management system and conformity to the referenced standards.

If the manufacturer holds any certifications (including, but not limited to, ISO 13485:2016) regarding the quality management system used for the manufacture of the product, then provide the requested information of such certification(s) in this section. The certification(s) must list all sites involved in the manufacture of the product.

Note that the manufacturer will be required to provide evidence of all quality management system claims as part of the product dossier submission.

8. Manufacturer – Sites of product manufacture

8.1. Sites of manufacture

Please provide all information required under this section about all sites that are involved in each and every stage of the manufacture of the product as per the table provided under this section. Please do not modify the description of the table.

8.2. Production

Provide information on the number of lots manufactured per year, their average size and the annual production volume of the product.

8.3. Key suppliers

Please provide all information required under this section about all key suppliers which supply products/components and/or services for the manufacture of the product (e.g. raw materials, critical components, sub-assemblies, electronics, software, sterile packaging, sterilisation services, or other manufacturing-related services).

9. Manufacturer declaration

The manufacturer declaration in this section of the pre-submission form must be completed, signed and dated on behalf of the manufacturer before the pre-submission form is considered for WHO's prequalification assessment. The declaration must be completed, signed and dated by a duly authorized representative of the manufacturer designated under section 1.2 of the pre-submission form.

Annex 1: Information to determine the product's eligibility for WHO's abridged prequalification assessment

If a regulatory version of the product submitted for WHO's prequalification assessment has not been stringently assessed and approved by any of the Recognized Regulatory Authorities listed in the WHO document PQDx_470 "*WHO's abridged prequalification assessment for medical devices*", but a stringently assessed and approved regulatory version of the product also exists (see information requested in section 6.1. of the pre-submission form), then please complete the table in Annex 1 with the requested information so that WHO may review and determine whether the product qualifies for an abridged prequalification assessment³.

Relevant documents

The following guidance documents provide information on the process for WHO's prequalification assessment of 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)
- WHO's abridged prequalification assessment for medical devices. Geneva: World Health Organization; (PQDx_470)
- Eligibility criteria for WHO's prequalification assessment of medical devices. Geneva: World Health Organization; (PQDx_465)

³ Refer to PQDx_470 "*WHO's abridged prequalification assessment for medical devices*" for an overview of WHO's abridged prequalification assessment.