Instructions for compilation of a medical device product dossier (non-in vitro diagnostic) for WHO's prequalification

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Contents

A. Introduction

This document provides instructions to manufacturers on the type of information and necessary documents that are to be submitted in a product dossier for WHO's prequalification assessment of medical devices.

Manufacturers[1] intending to submit a medical device product dossier for WHO prequalification assessment should consult the WHO document PQDx_464 "*WHO's prequalification procedure for medical devices"* and relevant WHO guidance before preparing and submitting the product dossier. This document should be read together with the "*Product dossier checklist for WHO's prequalification of medical devices"* (PQDx_469 and, where available, relevant WHO Technical Specification Series or Technical Report Series for the product (see section D)).

For the purpose of this document, the verbal forms used have the following meaning:

- "shall" indicates that the manufacturer is required to comply with the instructions in the document below.
- "should" indicates that the manufacturer is recommended to comply with the instructions, but it is not a requirement.
- "may" indicates that the instructions are a suggested method to compile the documentation request, but it is not a requirement.

B. The product dossier

B.1 About the product dossier

WHO expects a manufacturer to hold technical documentation that covers the full lifecycle of the device and provide timely access upon request. The product dossier is a selection of records and documents from this documentation, compiled to demonstrate conformity with internationally-recognized quality, safety and performance principles as described in the International Medical Device Regulators Forum (IMDRF) document IMDRF/GRRP WG/N47 FINAL[2] *Essential Principles of safety and performance of medical devices and IVD medical devices* (hereinafter "the Essential Principles").

B.2 Submission of a product dossier

WHO will inform the manufacturer if their product has been prioritised for prequalification assessment and request the manufacturer to submit their product dossier; a product dossier must not be submitted unless it has been requested in writing. If a prequalification application is accepted by WHO, WHO's prequalification assessment can take place through one of two pathways—namely, full or abridged prequalification assessment— as determined by WHO.

The rationale for abridged prequalification assessment is that a prior regulatory approval by a recognized regulatory authority provides a level of assurance relating to the product's quality, safety and performance in countries where it is approved, but it cannot always provide the same assurance when the product is used in other settings, including resource-limited settings (see the document PQDx_470 *"WHO's abridged prequalification assessment for medical devices").* If the product is eligible for an abridged assessment, the manufacturer will be notified in writing and requested to submit an abridged product dossier for the sections and subheadings listed in **Annex 1 - Abridged product dossier requirements** of this document.

WHO requires that a product dossier is submitted in the Table of Contents (ToC) structure that is described in the IMDRF document IMDRF/RPS WG/N9 FINAL[3] *"Non-In Vitro Diagnostic Device Regulatory Submission Table of Contents (nIVD ToC)"*. The chapters and subheading of this document are numbered according to the IMDRF ToC format. If a heading is **WHO prequalification specific**, it will be indicated as such. Not all subheadings listed in the IMDRF TOC are required for WHO prequalification and are excluded. As a result, the subheading numbering in the document below and the *"Product dossier checklist for WHO's prequalification of medical devices"* (PQDx_469) are not continuous (e.g. 4.2, 4.7 etc). This has been done to maintain consistency between sections required in a product dossier for WHO prequalification assessment and the corresponding numbering defined in the IMDRF ToC format.

[1] The definition of a "manufacturer" is found in document PQDx_464 "*WHO's prequalification procedure for medical devices"*.
[2] As amended from time to time
[3] As amended from time to time

WHO may request, during the course of the prequalification assessment, additional information that is not explicitly described in this document for a clearer understanding of the safety, efficacy and performance of a product under assessment. The rationale for any such requests will be clearly communicated to the manufacturer.

B.3 Applicability of supporting evidence to the product under review

The manufacturer shall conduct appropriate verification and validation activities to support the intended use of the medical device. These activities shall, as applicable, address device performance, safety, reliability, and robustness under normal and foreseeable conditions of use. Where relevant, investigations shall include assessment of environmental and use-related influences, stability over the claimed lifetime, and consistency of performance. Studies shall take into account the intended user, intended use, and intended use environment related to the product under assessment.

Not all sections and subheadings in the instructions below will be applicable to every submission, and manufacturers are required to provide only the information relevant to their device. Where a section is deemed not applicable, the manufacturer shall provide a documented justification within the product dossier. For example, some of the preclinical (non-clinical) testing, safety, performance and clinical evaluation parameters described in chapters 3 and 4 of this document may not necessarily apply to all types of products submitted for prequalification assessment.

Where a full study protocol and report is requested: the following shall be provided:

- Study Description: A description of the study that includes information to facilitate record traceability: study identifier, product identifier (for example, lot/batch numbers), IFU version used, the date of initiation and the date of completion. All data shall be clearly labelled and linked to the study report. This information is essential to establish the traceability, relevance, and representativeness of the study in relation to the specific product version submitted for WHO prequalification assessment.
- Full study protocol and report: The study protocol and full report, which incorporates at a minimum, the following information:

  a) complete, detailed description of the objective of the assessment, the methods and procedures.
  b) the site(s) where the study was performed (for example, manufacturers research and development laboratory, independent testing laboratory, clinical site, simulated use environment).
  c) study endpoint(s), pre-defined pass/fail criteria, deviations, results, discussion and conclusions (how the study supports the claimed performance and limitations, where relevant), and data.
  d) details of statistical methods, estimations and calculations applied.
  e) complete, detailed support of method selection, worst case justification, study endpoint selection, and pass/fail criteria shall be included.
  f) identification of critical equipment, instruments, software tools, and test systems used during the study that may impact study validity or measurement accuracy. Relevant calibration, qualification, maintenance, or validation of records shall be made available upon request.

- When performed by a party other than the manufacturer, details of this third party and the relationship to the manufacturer as well as copy of the contract between the manufacturer and the third-party identifying roles and responsibilities of each party.

Where a study summary is requested: the following shall be provided:

- Summary shall include a brief synopsis of the (1) purpose, (2) methods, (3) acceptance criteria, (4) results and (5) discussion and conclusions. Outliers and deviations shall be reported with the results. Results shall be stated quantitatively with appropriate statistical context where applicable (e.g. value ± SD, confidence intervals, etc.).
- The summary shall specifically address:

  a) Why the characteristic being evaluated is of interest;
  b) Why the particular methods are being used to evaluate the characteristic, if applicable including why a regional or harmonized/recognized standard/guidance has or has not been complied with;
  c) How the stated acceptance criteria and sample size are scientifically supported;
  d) What device was tested and how it relates to the devices that will be marketed;

e) Why the tested components are representative of the range of devices that will be marketed; and
f) The extent to which the duties and functions of a study (e.g. testing, monitoring, etc.) have been conducted by an external organization (e.g. contract research organisation or individual contractor).

Where no new testing has been undertaken for the device under assessment, but studies have been submitted for another device, the dossier shall incorporate a rationale for that decision, e.g. biocompatibility testing on the identical materials was conducted when these were incorporated in a previous, legally marketed version of the device. The rationale shall include:

a) a clear equivalence justification between the tested device and the device under assessment, based on relevant technical, biological, clinical, software, performance, manufacturing, and/or intended use characteristics, as applicable;
b) identification and traceability of the tested product(s), including device name, model/reference number, software version where applicable, manufacturing version, lot/batch number(s), and associated study identifiers; and
c) a justification demonstrating that any differences between the tested product and the device under assessment do not impact the applicability or relevance of the submitted evidence.

All documents submitted within the product dossier shall carry a document identifier, version number, and effective or approval date. Where a document has been revised, a brief revision history indicating the nature of changes shall be included. This applies to both manufacturer-generated documents and third-party reports.

C. Dossier format

C.1 Product dossier clarity and completeness

To facilitate an efficient and timely assessment, manufacturers shall ensure that all submitted documentation is clear, well-structured, and easily accessible. Where the presentation or organization of the dossier or specific documents significantly hinders the review process, WHO may request revised or reformatted documentation to improve clarity and navigability. Efforts shall be made to draft documents that concisely communicate the content described in the IMDRF document "*Non-In Vitro Diagnostic Device Regulatory Submission Table of Contents (nIVD ToC)".*

Manufacturers shall submit all applicable sections of the product dossier as identified in this document and in the *"Product dossier checklist for WHO's prequalification of medical devices"* (PQDx_469). Once the product dossier has been received by WHO, it will be screened for completeness before being reviewed. The manufacturer will be given two opportunities to submit the supplemental information and if this cannot be provided, then the product dossier will be rejected.

C.2 Product dossier submission format, layout and order

Submit one electronic application following the instructions provided in the letter of prioritization. WHO requires the following format for the dossier submission:

a) The ToC structure requirements apply for all prequalification applications (full and abridged).
b) A folder-based structure shall be followed, with files added within the structure. For example, the device description (Section 2.4.1 Comprehensive device description and principle of operation) may be provided in a folder in the electronic submission that is named "Section 2.4.1" or similar. The IMDRF Technical document "Assembly and Technical Guide for IMDRF Table of Contents Submissions" (IMDRF N27) provides assembly and technical information for building ToC submissions. It also includes the IMDRF standard ToC folder structure which can be used as a basis to assemble the submission content. Although archived, it can provide a useful background.
c) Consult the chapter headings and instructions in section E "Dossier content" below to identify the content and build the submission.
d) List all folders that are being submitted in the "*Product dossier checklist for WHO's prequalification of medical devices"* (PQDx_469).
e) Do not duplicate files, even if it is possible to include the same evidence under multiple subheadings. Provide the evidence under one appropriate subheading and then make specific references (including both section and page numbers) to that material in any subsequent sections that appear relevant.

f) Ensure that the submission meets the following formatting requirements:

- Pages of the submission shall be numbered in such a manner that information can be easily referenced by page number and section number. Use the page numbers format "page 1 of 2", "page 2 of 2" and section number, e.g. "Section 2.4.1", and so on. Number all pages of each section, including annexes, so that they are easily identified. The page numbers in each section of the dossier and the page numbers summarized in the "*Product dossier checklist for WHO's prequalification of medical devices"* shall correspond.
    - Font sizes for text and tables are of a style and size that are large enough to be easily legible. Fonts smaller than 11 points shall be avoided whenever possible, except in tables and footnotes where a font size of 10 points is acceptable.
    - Portable Document Format (PDF) is the preferred file format. However, do not include any PDF that requires a password to open it. This will result in return of dossiers to manufacturers resulting in the delay of the assessment.
- File names shall be meaningful and provide some indication of their content. The file name **must not exceed 120 characters**. The name can have spaces, dashes (not elongated dashes), underscores, and periods. However, the name of the file shall not contain any of the special characters such as slashes, quotation marks, asterisks, mathematical or non-ASCII symbols, as they are not compatible with WHO's storage platform.
- When creating a PDF from an electronic source document (e.g. Microsoft Word document), avoid using specialist application plug-ins for capture or display data; not all dossier reviewers will necessarily have access to these plug-ins.
    - As far as practicable, electronic files shall contain searchable text, electronic bookmarks and hyperlinks within tables of contents. Electronic files made by directly scanning paper documents are generally low quality and are difficult to read; moreover, the lack of searchable text can make dossier information difficult to readily locate and may delay assessment of the dossier.
    - For any scanned document, optical character recognition (OCR) shall 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.

C.3 Language and units of measurement

Information in the product dossier shall be in English. Any document provided in a language other than English shall be accompanied by a certified translation that is signed and dated by the translator and where the translator has stated that it is a true and accurate translation of the original document.

All measurements units used shall be expressed in the International System of Units (SI), as appropriate.

D. WHO guidance and specifications for WHO prequalification assessment

WHO has published specifications documents for certain medical devices as part of the **WHO Technical Specifications Series (TSS)** or as **WHO Technical Report Series (TRS)**. These documents are listed below[4] and flagged in the relevant sections of the product dossier below. The documents provide product-specific technical specifications relevant to WHO prequalification assessment and are available on WHO's website. Manufacturers shall ensure that they have referred to the current and applicable TSS/TRS annex for their product, where available, as these documents clarify general design, performance, labelling and packaging requirements to be submitted.

- Framework for clinical evaluation of devices for male circumcision. World Health Organization; 2012. https://iris.who.int/handle/10665/75954
- Screening of tuberculosis using computer aided detection software (Technical specifications series for submission to WHO prequalification - medical device assessment, TSS/MDV-01). Geneva: World Health Organization; 2025. Licence: CC BY-NC-SA 3.0 IGO. https://iris.who.int/handle/10665/381316.
- WHO Technical Report Series, No. 1025, 2020 available at https://iris.who.int/handle/10665/331814

[4] List may be amended from time to time

- Annex 10 World Health Organization/United Nations Population Fund technical specifications for male latex condoms.

- WHO Technical Report Series, No. 1044, 2022 available at https://iris.who.int/handle/10665/365397
  - Annex 9 WHO/UNFPA guidance on natural rubber latex male condom stability studies.
  - Annex 10 WHO/UNFPA technical specification for TCu380A intrauterine device.
- WHO Technical Report Series, No. 1052, 2024 available at https://iris.who.int/handle/10665/376607
  - Annex 5 WHO/UNFPA female condom generic specification.
- WHO Technical Report Series, No. 1033, 2021 available at https://iris.who.int/handle/10665/340323
  - Annex 5 World Health Organization/United Nations Population Fund Recommendations for condom storage and shipping temperatures.
- WHO Technical Report Series, No. 1067, 2025 available at https://iris.who.int/handle/10665/386361
- Annex 6 World Health Organization/United Nations Population Fund specifications for personal lubricants.

In addition, the following documents and webpages provide information to guide the manufacturer through WHO's prequalification assessment.

- https://extranet.who.int/prequal/medical-devices
- Product dossier checklist for WHO's prequalification of medical devices. Geneva: World Health Organization; (PQDx_469)

In addition to WHO-specific guidance documents and technical specifications, the WHO's prequalification assessment of medical devices is performed considering internationally recognized medical device regulatory principles, applicable international standards, relevant guidance documents, and the current state of the art for the product concerned.

Manufacturers shall identify and justify the standards, guidance documents, methods, and other state of the art references considered during the design, development, verification, validation, and lifecycle management of the device. These elements shall be listed and submitted within the product dossier, including in Section 2.10 (Standards), as applicable.

E. Dossier content

The following pages provide important guidance and information regarding the content, structure, and supporting evidence expected within the product dossier submitted for WHO prequalification assessment.

1. Regional administrative

1.1 Letter of agreement (WHO prequalification specific heading)[5]

WHO prequalification specific content: The completed letter of agreement, including an attestation demonstrating payment of fees shall be included in this section.

1.2 Product dossier checklist (WHO prequalification specific heading)[6]

WHO prequalification specific content: The "*Product dossier checklist for WHO's prequalification of medical devices"* (PQDx_469) shall be provided in this folder. The checklist shall be signed, dated and include a declaration attesting that all the information provided in the product dossier is current and correct.

This checklist will serve as the basis for the initial screening and completeness assessment of the product dossier.

1.3 List of terms/acronyms

Abbreviations used in this submission shall be defined here.

1.4 Application form/administrative information

A copy of the final, signed, completed "*Pre-submission form for WHO's prequalification assessment of medical devices"* shall be included in this section.

1.5 Listing of device(s)

In this section, the manufacturer shall provide a table listing each model / configuration / component / accessory that is the subject of the submission and the following information for each model:

- the identifier (e.g. product code, catalogue, model or part number, UDI)
- a statement of its name/description (e.g. Trade name, size, material)

This information shall be consistent with that provided in the WHO Letter of Agreement. Please note, a detailed description of configurations/variants is provided in section 2.4.1.

1.6 Quality management system (QMS), full quality system or other regulatory certificates

In this section, the manufacturer shall provide evidence of a valid quality management system, such as an International Organization for Standardization (ISO) 13485[7] certificate issued by a conformity assessment body. The product under assessment shall be within the scope of the certification. Certification according to the Medical Device Single Audit Program (MDSAP) may also be provided as evidence of an audited QMS, where the audit scope includes ISO 13485 and covers the product under assessment.

The submitted certificate(s) shall clearly identify:

a) the legal manufacturer;
b) the manufacturing site(s) covered;
c) the scope of activities and products covered; and
d) the certificate number and validity dates.

If available, the weblink that can be used to verify this certificate shall be provided.

[5] Although WHO prequalification request for a signed letter of agreement, this heading in the context of the IMDRF nIVD ToC is 1.1 Cover letter
[6] This heading in the context of the IMDRF nIVD ToC is 1.2 Table of contents
[7] As amended from time to time

If no ISO 13485 certificate is available, the manufacturer shall provide documented evidence demonstrating the existence and implementation of an equivalent QMS.

Note 1: ISO/International Electrotechnical Commission (IEC) 42001 provides guidance on requirements of QMS to support artificial intelligence (AI)-based technologies.

1.7 Free sale certificate/certificate of marketing authorization

In this section, the manufacturer shall (if applicable):

a) List the national regulatory authorities that have provided current regulatory approval for the supply of this product in their country/region of authority;
b) Provide details of the type of regulatory approval obtained from each national regulatory authority (e.g., market authorization, conformity assessment resulting in CE marking, national registration or clearance, or export-only authorization);
c) Confirmation that each approval is current, valid and not subject to suspension, restriction or withdrawal.; and
d) Provide current evidence of regulatory approval, such as certificates/letters provided by the national regulatory authority or official representative (e.g. notified body) for same version that is being submitted. Copies must be certified by a notary public or by the manufacturer.

The evidence provided shall clearly show that the manufacturer and the product under assessment falls within the scope of the submitted regulatory approval. Information relating to export-only regulatory approvals shall be clearly identifiable as export-only approvals.

1.12 Statements/certifications/declarations of conformity

1.12.5 Truthful and accurate statement

No information here. The declaration attesting that all the information provided in the product dossier is current and correct is included as part of Section 1.2 Product dossier checklist.

1.12.7 Declaration of conformity

The manufacturer shall provide a Declaration of conformity for the device declaring that it complies with the following:

a) The regulatory framework under which the device has been assessed (e.g. EU MDR, UK MDR 2002, or other national regulatory system);
b) The applicable provisions of the Essential Principles/Requirements:
c) The applicable classification rules; and
d) The conformity assessment procedure applied.

For devices that have not yet been placed on the market and have not undergone regulatory assessment under a specific jurisdiction, the manufacturer shall provide a declaration identifying the international regulatory framework and guidance documents being followed during product development and conformity assessment activities.

2. Submission context

2.4 Device description

Product specific requirements are found in the Technical Report series Annexes and Technical Specification series documents listed in Section D above. It is important that manufacturers refer to these documents when preparing their submission.

2.4.1 Comprehensive device description and principle of operation

The dossier shall include product descriptive information sufficient to allow a dossier reviewer to understand the design applied to the product and how it functions. The instructions for use (IFU) may be used to provide some of this information, on the condition that it is clearly indicated in the dossier what information can be found in the IFU. **Not all listed information applies to all devices.**

The following information shall be provided in this section (where applicable):

a) A general description of the device, including:
   i. A statement of the device name;
   ii. Device category/type (e.g., implantable, active therapeutic, non-active, reusable, single-use);
   iii. Risk classification and rationale to justify the classification;
   iv. Intended Use and Purpose (may be provided in section 2.5);
   v. Intended Population and Medical Condition/Indication (may be provided in section 2.5);
   vi. Where to use it? (places/environment where the device is intended to be used) (may be provided in section 2.5);
   vii. How it works? Including a description of the features/variants/operating modes that enable the device to be used for indications/intended use (principle of operation/mechanism of action) and if not readily apparent or typical for the device type, a brief description of the underlying science/technology, design concepts, and/or theoretical principles supporting the device's function;
   viii. If applicable, labelled pictorial representation (diagrams, photos, drawings);
   ix. If system, how the components relate?;
   x. If applicable, identify if the device incorporates software/firmware and its role; and
   xi. Identification of the exact product configuration submitted for prequalification, including models, variants, sizes, components, accessories, kits, software versions, packaging configurations, and any elements supplied separately but intended to be covered by the application.

b) Product specification, including:
   i. Physical characteristics of relevance to the end user (e.g. dimensions, weight);
   ii. Features and operating modes;
   iii. Input specifications (e.g. electrical power requirements, settings and associated allowable ranges/limits);
   iv. Output and performance characteristics (e.g. range and type of energy delivered, resolution of images); and
   v. If applicable, an indication of the variants/models of the devices and a summary of the differences in specifications of the variants (comparison table and/or pictures/diagrams with supporting text).

c) List of accessories intended to be used in combination with the device.
d) Indication of any other medical devices or general product intended to be used in combination with the medical device.
e) Components or accessories that can be sold separately shall be identified.
f) If approved by a recognized regulatory authority, provide the approval number and identification for each component or accessory.
g) If the device is to be sterilized before use, an indication of who is to perform the sterilization and by what method (e.g. EtO, gamma irradiation, dry heat) **OR** an affirmative statement that the device is non-sterile when used.
h) Summary of the composition of the device including, at minimum, the material specification and/or chemical composition of the materials that have direct or indirect contact with the user and/or patient (including coatings, lubricants, additives, colorants, active components, medicinal substances, and any substances intentionally incorporated or expected to come into direct or indirect contact with the user or patient). When required, full details to support how these specifications are met shall be provided in 3.5.02 – Chemical/Material Characterization.

NOTE: If applicable, chemicals may be identified using either the IUPAC (International Union of Pure and Applied Chemistry) or the CAS (Chemical Abstract Service) Registry number. Reference to applicable material standards may also be useful in this description.

i) If applicable, indication of biological material or derivate used in the medical device, including origin (human, animal, recombinant or fermentation products or any other biological material), source (e.g. blood, bone, heart, any other tissue or cells), and the intended reason for its presence and, if applicable, its primary mode of action.
j) If the device contains an active pharmaceutical ingredient (API) or drug, an indication of the substance, shall be provided. This shall include its identity and source, and the intended reason for its presence and its primary mode of action. Where applicable, the regulatory status of the medicinal substance shall be provided, including evidence of its approval or authorisation by a recognised regulatory authority, or reference to applicable pharmacopeial standards.
k) Engineering diagrams/prints/schematics of the device (shall be provided as a separate file within the submission).

2.4.2 Description of device packaging

In this section the manufacturer shall provide:

a) Description of the primary packaging (i.e. packaging in direct contact with the device);
b) Description of secondary and tertiary packaging, where applicable;
c) Indication of whether the packaging constitutes a sterile barrier system (if applicable);
d) The packaging configuration of any accessories supplied or marketed together with the medical device shall be clearly described; and
e) Where the user is required to package the medical device or its accessories prior to sterilization, detailed instructions on the appropriate packaging specifications shall be provided. This shall include information on suitable materials, composition, dimensions and any other relevant characteristics necessary to ensure effective sterilization.

2.4.3 History of development

a) In this section, the manufacturer shall provide the date of design lock down (design freeze).
    - For prequalification assessment, “design lockdown” is a formal milestone in the 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.

Note 2: Changes that occur after design lock-down must be documented and evaluated within the framework of change management and risk-management procedures. Refer to the Changes guidance for further information on classification of reportable changes.

b) Provide a brief overview of previous device generation(s), where applicable, focusing only on major differences compared to the current version.
c) Provide a concise statement confirming whether changes occurred after design lock-down:
    - If **no changes** → state explicitly
    - If **changes occurred** → refer to Table 1 below
d) Provide a table with information on the change using the table below as a guide to the column headings and information to be provided.

Table 1 – High-Level Overview of Changes Between Generations

Device Version	Type of Change	High-Level Description	Impacted Area	Overall Impact
V1 → V2	*Software / Design / Performance*	*Algorithm updated for improved sensitivity*	*Performance*	*Improved*
V2 → V3	*IFU / Intended Use*	*Clarification of intended population*	*Intended Purpose*	*No impact*

e) When completing the table, the following level of detail is requested:
    - Include only major/substantial changes
    - Use **high-level descriptions only** (1 line per change)
    - Do **not include detailed rationale or V&V here**
    - Focus mainly on changes impacting:
        - Intended purpose
        - Functionality
        - Performance
        - Safety

f) Where a design change has occurred since the date of design lock down, the manufacturer shall provide records of each such change, as per table below:

Device or Technical Documentation Version	Software version (when applicable)	Key Changes vs Previous Version	Rationale	V&V / Clinical Evidence
V1.0	SWV 1.1.1	Initial release	—	—

V2.0	SWV 2.3.4	Algorithm update	Performance improvement	Study Y

g) The design change table above shall:
- Include only device versions relevant to the evidence submitted in the dossier.
- Focus on changes that may impact the intended purpose, functionality, performance, safety, or critical components/materials of the device.
- Exclude administrative or non-product-related changes, including:
    - QMS-related updates or administrative changes.
    - manufacturing changes that do not impact product performance or safety .
    - labelling or IFU updates that do not affect intended use, performance, or safety.

Note: Software version and revision level history requirements are described under section heading 3.5.5.9 below.

2.4.4 Reference and comparison to similar and/or previous generation of the device

The manufacturer shall provide the following information in this section:

a) A list of similar devices (available on local and international market) and/or previous generation of the devices (if existent) relevant to the submission. This shall include any similar/previous generation devices that were previously reviewed and refused by the subject regulator.
b) A brief rationale for the selection of the identified similar devices.
c) A comparative summary of key specifications (preferably in a table), between the subject device and the identified similar/reference devices.

2.5 Indications for use and/or intended use

2.5.1 Intended use; Intended Purpose; Intended User; Indications for Use

In this section, the manufacturer shall provide a description of the intended use, purpose, the intended user and indications for use of the product, **which must be as provided on the labelling**. If more than one device is included, the information shall be provided for each device.

This section shall provide sufficient detail to allow it to be understood[8]:

d) **Intended Use:** The statement of intended use shall specify the therapeutic or diagnostic function provided by the device and may describe the medical procedure in which the device is to be used (e.g. diagnosis, treatment, monitoring, rehabilitation, contraception, disinfection, surgical intervention).
e) **Intended Purpose:** What is expected with the use of this medical device? Which results are expected?
f) **Intended user:** Skills**/**knowledge/training that the user shall have to operate or use the device.
g) Identify if the device is intended for **single or multiple use.**
h) Indications for Use:
    - Disease or medical condition that the device will diagnose, treat, prevent, mitigate or cure, parameters to be monitored and other considerations related to indication for use;
    - If applicable, information about patient selection criteria; and

    i. If applicable, information about intended patient population (e.g. adults, paediatrics or newborn) or a statement that no subpopulations exist for the disease or condition for which the device is intended.

[8] Definitions relevant to this section are found in the GHTF document “Glossary and Definition of Terms Used in GHTF Documents GHTF/SC/N4:2012” available at /www.imdrf.org

2.5.2 Intended environment/setting for use

i) The setting where the device is intended to be used (e.g. domestic use, hospitals, medical/clinical laboratories, ambulances, medical/dental offices). Multiple options can be indicated.
j) If applicable, environmental conditions that can affect the device's safety and/or performance (e.g. temperature, humidity, power, pressure, movement).

2.5.4 Contraindications For Use

If applicable, specify the disease or medical conditions that would make use of the device inadvisable due to unfavourable risk/benefit profile and as presented in the labelling.

2.6 Global market history (commercial history)

2.6.1 Global market history

Different regulatory requirements apply to different international markets for medical devices. Manufacturers who market their medical devices to multiple countries often alter some aspects of their products to comply with regional regulatory requirements and marketing needs (e.g., differences in design or configuration, information within the instructions for use, different intended use statements, different manufacturing or quality control processes, different manufacturing sites, different labelling and/or packaging information). If such various versions of a product exist, WHO must have a clear understanding of precisely which version of the product the manufacturer is seeking to be prequalified. In this section:

a) Identify if there are multiple regulatory approved or marketed versions of this product. If the product has multiple regulatory versions, clearly indicate which regulatory version of the product the manufacturer submitted for WHO prequalification assessment.
b) Identify the version that is being submitted for WHO prequalification assessment. If the version has not been assessed in any jurisdiction, indicate this.
c) Ensure that all documents submitted in the product dossier identify the medical device version to which they relate. Where a document does not relate to the version submitted for WHO prequalification assessment, a justification for its inclusion in the product dossier shall be provided. If the subject device is different in any way (e.g. design, labelling, specifications) from those approved or marketed in other jurisdictions, the differences shall be described.
d) Provide a list of all countries in which the product under assessment is currently supplied and the year when supply started. If the device has been marketed for greater than 10 years, a statement to this effect can be provided. This includes all countries where the device has been made available, whether in return commercially or free of charge, for distribution and/or use in that country.
e) Provide the number of devices sold or distributed (placed on the market) for the last 2 years.

2.6.2 Incident reports and recalls

In this section, the manufacturer shall provide:

f) A list of all adverse events within the last five years that did affect, or could have potentially affected, the safety and/or performance of the medical device, the safety of patients, users, or other persons exposed to the device. Include details of the corrective and preventive action taken;
g) Details regarding any situations in which the product was rejected by a national regulatory authority, situations in which an application for regulatory approval was withdrawn, or situations in which regulatory approval has been withdrawn. Include details of the corrective and preventive action taken; and
h) A list of all events within the last five years that required field safety corrective action such as:

- Withdrawal of products from sale or distribution;
- Physical return of the product to the manufacturer;
- Product exchange;

- Destruction of the product;
- Product modification(s); and
- Additional advice provision to customers to ensure that the product continues to function as intended.

2.8 Risk management

A risk management process shall be established, implemented and maintained for the medical device in accordance with a recognised risk management standard (e.g. ISO 14971 or equivalent).

A risk analysis shall be undertaken to identify and address all known or foreseeable hazards related to the medical device, taking into account such aspects as the intended user(s) of the device, and the technology involved.

The information provided in this section shall contain:

a) A summary report of the risks identified during the risk analysis and risk management process, including as applicable but not limited to:
    - Risks to patients or users arising from device malfunction, failure to perform as intended, degradation or use error;
    - Risks related to material properties, biocompatibility, sterility (if applicable), and chemical characteristics;
    - Risks associated with mechanical failure, electrical hazards, thermal effects, radiation, or energy delivery;
    - Software-related risks, including failure of embedded or stand-alone software and cybersecurity (where applicable);
    - Environmental influences that may impact device safety or performance;
    - Risks associated with delayed, interrupted, or unavailable device functionality where timely performance is critical to patient care or management;
    - User-related hazards, including foreseeable misuse and those associated with device handling, human-machine interaction, use errors, or exposure to hazardous substances or components, where applicable;
    - Manufacturing and production-related risks that may impact device quality, safety, or performance; and
    - Risks arising from the use of the medical device by users with minimal skills, training or experience and in the intended settings of use.
b) A description of how the identified risks have been reduced to an acceptable level through the implementation of risk control measures as part of the manufacturer's risk management process. This may be demonstrated by provision of documented evidence included in the risk management file such as failure modes and effects analysis (FMEA), failure reporting and corrective action system (FRACAS), fault tree analysis (FTA) or equivalent methods, as applicable.
c) Activities implemented to demonstrate the efficiency of the risk control measures.
d) Measures implemented to inform and communicate to users any residual risks.
e) A conclusion with evidence that the overall residual risk is acceptable when compared to the benefits. This conclusion shall be dated and signed by senior management.
f) Evidence that the risk management activities are part of the manufacturer's established risk management process and plan, including reference to the risk management file (or equivalent documented evidence).
g) Where a recognized standard has been followed, identify the relevant standard(s) and edition(s).

2.9 Essential Principles (EP) checklist

The product dossier shall provide evidence of conformity to the "Essential Principles" as outlined in the

IMDRF document IMDRF/GRRP WG/N47:FINAL[9] "*Essential Principles of safety and performance of medical devices and IVD medical devices"*. Conformity to the Essential Principles shall be summarized in an Essential Principles checklist, a table that includes:

a) Whether each Essential Principle applies to the product and if not, a justification for why this is not the case.
b) The method used to demonstrate conformity with each relevant Essential Principle, as well as the reference for the method used.
c) A reference to specific technical documentation that demonstrates conformity to each relevant Essential Principle (where such documentation is specifically required for inclusion in the product dossier, its location in the product dossier shall be provided).
d) Identification of specific standards or guidelines referenced, as appropriate.

2.10 Standards

2.10.1 List of standards and guidance documents

This section shall include:

a) If applicable, a list of the standards that have been complied with in full or in part in the design and/or manufacture of the device.
    i. At a minimum the list shall include the standard organization, standard number, standard title, year/version, and if full or partial compliance.
    - If partial compliance, the manufacturer shall list the sections of standard that: are not applicable to the device;
    - have been adapted; and/or
    - were deviated from for other reasons – discussion to accompany.
b) If applicable, a list of relevant guidance documents published by regulators and referenced in the design and/or manufacture of the device with the jurisdiction of publication, publication date and title identified.
c) If applicable, a list of relevant clinical guidelines referenced in the design and/or manufacture of the device, the publisher, publication date and title identified.

2.11 Other submission context information

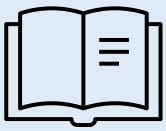
*2.11.1 Training and support networks **(WHO prequalification specific heading)***

WHO prequalification specific content: The following detailed information about the training and support network that is available in each country of supply shall be provided:

d) How the users are trained in the safe and effective use of the medical device;
e) How installation, configuration, servicing, maintenance, and repair activities are performed, where applicable, including the roles of the manufacturer, authorized representatives, or trained service providers;
f) How users and service personnel contact the supplier or manufacturer for technical support, including reporting of device-related issues; and
g) A statement as to whether there are representatives located in each country of supply to provide technical support; and if so, how many.

[9] As amended from time to time

3. Non-clinical evidence



Specific requirements for non-clinical studies can also be found in the Technical Report series Annexes and Technical Specification series documents listed in Section D above. It is important that manufacturers refer to the documents relevant to their medical device when preparing their submission.

This section shall include the non-clinical laboratory studies conducted to characterise and verify the physical and mechanical properties of the medical device. The purpose of this section is to demonstrate that the device meets its design specifications and performs safely and effectively under anticipated conditions of use.

3.5 Non-clinical studies

3.5.1 Physical and mechanical characterization

Studies that support the physical or mechanical properties of the subject device are to be included in this section. This shall include:

a) A summary of the non-clinical testing and evidence relevant to the physical and mechanical characteristics of the medical device.
b) A discussion as to what tests were considered and why they were or were not performed
c) Full study protocols and reports as described in section B.3.
d) If applicable, particulate testing from wear or device coatings. Cross-reference to biological evaluation studies where particulate generation may impact safety.
e) Discussion to support why the evidence presented is sufficient to support the applicable safety and performance requirements.

3.5.2 Chemical/Material Characterization

Tests that describe the chemical or material composition of the device and its components shall be provided. This shall include:

a) A summary of the non-clinical testing and evidence.
b) A discussion as to what tests were considered and why they were or were not performed.
c) Full study protocols and reports as described in section B.3.
d) A discussion to support why the evidence presented is sufficient to support the application.

3.5.5 Software/Firmware/Programmed or programmable medical device

Studies and supporting information on the software design, development process and evidence of the validation of the software, as used in the finished device, are to be included in this section and the associated sub-sections. It shall also address all the different hardware configurations and, where applicable, operating systems identified in the labelling. Documentation shall be organized according to software or hardware systems.

3.5.5.1 Software/Firmware Description

Provide a description of the medical device software sufficient to understand its purpose, functionality, and operational context. The documentation shall include:

a) Software name and unique identifier where applicable.
b) Overview of the software functionality and key features, including its intended use and operating context.
c) Software version identification corresponding to the version assessed. Any differences between the tested and released versions shall be explained.
d) Identification of device functions controlled by the software, including safety-related functions, where applicable.
e) Description of the algorithmic logic and, where applicable, a detailed description of the algorithm(s) or model(s) used to achieve the intended medical purpose.
f) Description of the software environment, including programming language, operating system (if applicable), hardware platform, and use of off-the-shelf (OTSS) or third-party software components.
g) Where applicable, documentation shall identify the software safety classification applied and the level of rigor applied to the development and verification activities.

Where the device incorporates artificial intelligence (AI) or algorithm-based functionality (e.g. machine learning, neural networks, expert systems, natural language processing), documentation shall include, where applicable:

a) Description of the algorithms or models used, including inputs, outputs, and decision logic.
b) Identification of the model (name, unique identifier, and version) and its correspondence to the released software version.
c) The model type and architecture (e.g. classifier, regression, neural network) and the rationale for its selection.
d) The clinical task performed by the model (e.g. detection, classification, prediction, quantification), the model inputs and outputs, and the meaning of the outputs within the clinical workflow.
e) An explicit statement that the model is locked at release.
f) The intended-use population and operating conditions for which the model is validated, and the known limitations, contraindications, or out-of-scope inputs.
g) Risk management considerations addressing algorithm performance, failure modes, model drift, and human oversight.
h) Information supporting transparency or interpretability of algorithm outputs, where relevant.
i) Post-market monitoring approaches for algorithm performance and control of updates or modifications.

3.5.5.2 Risk Management File (including Hazard Analysis)

a) The risk management file shall be provided and include the risk management plan, risk assessment (e.g. hazard analysis), and risk management report.
b) The risk assessment (e.g. hazard analysis) shall take into account all device hazards associated with the device's intended use, including both software hazards and hardware hazards (where there is device-specific hardware).
c) For software that is part of a system, a risk assessment shall be performed on the system comprising the software and its whole hardware environment and noted in the software documentation with reference to the particular section of the product dossier.
d) Risk control measures identified through the risk management process shall be allocated to the relevant software functions, software items, or software units and reflected in the design and verification documentation.

3.5.5.3 Software Requirement Specification (SRS)

a) Provide documentation describing the requirements for the medical device software.
b) The SRS shall present the functional, performance, safety, cybersecurity, usability, and data-related requirements applicable to the software.
c) The SRS shall additionally include:

- Specification of the software operating environment, including hardware platform, operating system, network infrastructure, and any other software dependencies;
- Interface requirements, covering user interfaces, hardware interfaces, and interfaces with external software systems;
- Requirements allocated to third party software (SOUP/OTSS), including expected functional behaviour, performance, and anomaly handling; and installation, configuration, and acceptance requirements applicable to the software system.

d) The requirements documentation shall demonstrate alignment with:
   - Risk management outputs;
   - Usability engineering considerations;
   - Cybersecurity requirements; and
   - Applicable regulatory safety and performance requirements.
e) Where relevant, requirements related to AI-based functionality (e.g., transparency, human oversight, performance monitoring, or change management) shall also be addressed.
f) The documentation shall enable traceability between requirements and the corresponding design, risk control, and verification activities.
g) Requirements shall be defined with sufficient clarity and level of detail to support design implementation, verification activities, and maintenance of the software.

3.5.5.4 System and Software Architecture Design (SAD) Chart

a) The manufacturer shall provide detailed diagrams/documentation describing the system and software architecture, including major components, modules, interfaces, and data flows.
b) The architecture documentation shall describe
   - How software elements interact with each other, with hardware components, and with external systems or users;
   - The decomposition of the software system into software items and, where applicable, software units, including the allocation of functional and safety-related requirements to the relevant software items or software units.

In addition, the following information shall be provided:

c) An explanation of the safety, performance or clinical relevance of each main component, including its potential impact on the intended medical purpose, device outputs, data integrity, user interaction and risk control measures shall be provided;
d) Where applicable, the manufacturer's categorisation of the criticality of software components, with rationale and traceability to risk management outputs shall be provided:
e) Identification of off-the-shelf, third-party or externally developed software components, including their role and interfaces within the architecture shall be provided;
f) A description of any segregation, isolation or interface-control mechanisms implemented between components with different criticality profiles shall be provided, where applicable;
g) A rationale for safety-relevant architectural decisions, sufficient to demonstrate that the selected architecture supports the risk control strategy and intended performance shall be provided; and
h) Where architectural diagrams are included in other documentation, the relevant location shall be referenced.

3.5.5.5 Software Design Specification (SDS)

a) Provide documentation describing the design of the software and how the software architecture implements the requirements defined in the SRS.
b) The design documentation shall describe software components, interfaces, data handling, and control logic sufficient to understand the implementation of functional and safety-related requirements.
c) Where applicable, the documentation shall also address

- Allocation of risk control measures;
- Cybersecurity design considerations; and
- Usability-related design controls.

d) For software incorporating AI-based functionality, documentation shall describe the integration of the algorithm or model within the software architecture and relevant control mechanisms.
e) The design documentation shall provide sufficient detail to support verification of the implemented requirements and to enable maintenance or modification of the software.
f) Traceability between design documentation, requirements, and risk management outputs shall be evident.

3.5.5.6 Traceability Analysis

A Traceability Analysis shall be provided which links together the product design requirements, design specifications, and testing requirements. It also provides a means of tying together identified hazards with the implementation and testing of the mitigations.

3.5.5.7 Software Life Cycle Process Description / Software Development, Configuration Management, and Maintenance Practices

Describe the software development life cycle and the processes in place to manage the relevant life cycle activities, including software planning, requirements management, design and implementation, verification and validation, release, configuration management, change control, maintenance, problem resolution, and decommissioning where applicable.

The documentation shall describe

- the development model used;
- the roles and responsibilities;
- the applicable procedures;
- the tools and environments used for development and testing; and
- and the controls implemented to ensure traceability between software requirements, design, risk control measures, verification and validation activities, unresolved anomalies, and released software versions.

For software incorporating artificial intelligence or machine learning components, the documentation shall also describe the specific life cycle controls applicable to the AI/ML model. This shall include, as applicable, the processes for data management and governance, including data sourcing, curation, storage, access control, dataset partitioning and prevention of data leakage; the establishment of ground truth or reference standards; the management of data quality, representativeness and potential bias; and the applicable data protection and privacy controls.

The documentation shall further describe the model development and training process, including the training methodology, model selection approach, use of third-party or pre-trained components, configuration management and versioning of the model artefact, training data, code and development environment. The released model configuration shall be clearly identified. Where the model is not intended to adapt after release, the documentation shall confirm that the model is frozen and that no further training occurs in the field.

Detailed evidence supporting model performance, bias assessment, clinical performance or post-market monitoring may be provided in the relevant sections of the submission and cross-referenced here.

3.5.5.8 Software Testing as Part of Verification and Validation

Provide an overall description of the verification and validation activities performed for the final software version. Provide the applicable test protocols and reports including the expected results, observed results and pass/fail determination.

For software incorporating artificial intelligence or machine learning components, the verification and validation documentation shall include evidence that the final released model has been tested against predefined acceptance criteria using appropriate and independent datasets. The documentation shall describe, as applicable, the test dataset, performance metrics, statistical methods, robustness testing, assessment of relevant subpopulations and bias, and testing of AI-generated outputs such as alerts, alarms, recommendations or classifications. The results shall demonstrate that the model performance, limitations and failure modes are acceptable for the intended purpose and conditions of use.

3.5.5.9 Software Version / Revision Level History

Provide the history of software versions that were tested and documented as part of verification and validation activities.

a) This typically takes the form of a line-item tabulation including the date, version number that was tested and a brief description of all changes in the version relative to the previously tested version.
b) The last entry in a line-item tabulation shall be the final version to be incorporated in the released device. This entry shall also include any differences between the tested version of software and the released version.

3.5.5.10 Unresolved Software Anomalies

Documentation shall include a list of unresolved anomalies present in the software with the following items (e.g. in tabular format) for each unresolved anomaly:

a) A description of what the anomaly is and what root cause(s) of the anomaly could be;
b) Identification of how the anomaly was discovered and, where possible, identification of the root cause(s) of the anomaly;
c) Evaluation of the impact of the anomaly on the device's safety and effectiveness, including operator usage and human factors considerations;
d) Outcome of the evaluation; and
e) Risk-based rationale for not correcting or fixing the anomaly in alignment with the risk management plan or procedure(s).

3.5.5.11 Cybersecurity

Evidence to support the cybersecurity solutions shall be provided, including but not limited to:

a) Cybersecurity vulnerability and risk analysis.
b) Cybersecurity control measures.
c) A traceability matrix linking cybersecurity controls to the cybersecurity vulnerabilities and risks.

In relation to the cybersecurity of their medical device, the manufacturer shall provide information on hazard analysis, mitigations and design considerations pertaining to intentional and unintentional cybersecurity risks associated with the device, including:

d) A specific list of all cybersecurity risks that were considered in the design of the device.
e) A specific list and justification for all cybersecurity controls that were established for the device.
f) A traceability matrix that links the actual cybersecurity controls for the cybersecurity risks that were considered.
g) A summary of the plan for providing validated software updates and patches as needed throughout the life cycle of the medical device, to continue to assure its safety and effectiveness.
h) A summary of the controls that are in place to assure that the medical device software will maintain its integrity (e.g. remain free of malware) from the point of origin to the point at which that device leaves the control of the manufacturer.
i) The device IFU and product specifications related to recommended cybersecurity controls appropriate for the intended use environment (e.g. anti-virus software or use of a firewall).

3.5.5.12 Interoperability

If the device can communicate with other devices. Evidence to support the interoperability shall be provided.

3.5.6 Biocompatibility and Toxicology Evaluation

Studies supporting biocompatibility and assessing toxicology shall be included in this section to support the biological evaluation of the device. Studies to assess the immunological response to animal or human tissues, tissue components or derivatives shall be included where applicable as described below.

a) Tests shall be performed in ISO/IEC 17025 accredited laboratories.
b) Biological Evaluation Plan (BEP) (where available), describing the biological evaluation strategy and including:
    - Identification and justification of the biological endpoints to be evaluated;
    - Risk-based justification for the selection or omission of biological endpoints, considering device classification, nature and duration of body contact, material composition, manufacturing processes, and sterilization method; and
    - Where applicable, the strategy for chemical characterization and toxicological risk assessment.
c) Biocompatibility/Toxicology and Biological Safety Studies
    - Full study protocols and reports as described in Section B.3;
    - A list of all materials and substances in direct or indirect contact with the patient or user, including the nature and duration of contact; and
    - Identification of applicable standards, guidance documents, and test methods applied.
d) Biological Evaluation Report (BER)
    - A consolidated evaluation of all biological safety data, including biocompatibility, chemical characterization, toxicological assessments, and other relevant biological investigations;
    - Conclusions regarding residual biological risks and their acceptability within the overall benefit–risk determination; and
    - A discussion demonstrating that biological risks have been adequately identified, evaluated, controlled, and reduced as far as possible.

NOTES:

e) Tests shall be conducted on samples from the finished, final-processed device, including sterilization where the device is supplied sterile, and representative of the final manufacturing process.

3.5.9 Sterilization and Reprocessing Validation

3.5.9.2 Manufacturer Sterilization Validation

Where the device is supplied sterile, the dossier shall contain the detailed information of the manufacturer's sterilization validation, demonstrating that the process consistently achieves the intended Sterility Assurance Level (SAL) without adversely affecting device safety or performance. This shall include:

a) A description of the sterilization process (method, parameters) and Sterility Assurance Level (SAL), including justification for the selected SAL and reference to applicable standards where relevant.
b) Confirmation that validation was performed on the final finished device configuration, including packaging.
c) State if parametric release is used, and provide justification and supporting validation data where applicable.
d) A summary of the non-clinical evidence that falls within this category, including bioburden and sterility testing where applicable.

e) For relevant sterilization methods, confirmation that residuals, degradation products, or process-related effects (e.g. EtO residuals, radiation effects) have been evaluated and are within acceptable limits.
f) Information on the ongoing revalidation of the process. Typically, this would consist of arrangements for, or evidence of, revalidation of the packaging and sterilization processes, including periodic review and maintenance of validated state.
g) A discussion of the non-clinical testing considered for the device and support for their selection or omission from the verification and validation studies conducted in this category (i.e., what tests were considered and why they were or were not performed), considering a risk-based approach.
h) Discussion to support why the evidence presented is sufficient to demonstrate that the sterilization process consistently achieves the intended level of sterility without adversely affecting device safety or performance.
i) Validation documentation (including, where applicable, validation protocols and full validation reports) of manufacturer sterilization where the device is provided sterile shall be included (as per section B.3 above).

3.5.9.3 Residual Toxicity

The dossier shall contain information on testing for sterilant residues, where the device is supplied sterile and sterilized using a method susceptible to residues. This shall include:

a) A summary of the non-clinical evidence that falls within this category, including reference to applicable standards where relevant (e.g. ISO 10993-7 for ethylene oxide residues).
b) A discussion of the non-clinical testing considered for the device and support for their selection or omission from the verification and validation studies conducted in this category (i.e., what tests were considered and why they were or were not performed), considering a risk-based approach and the nature and duration of device contact.
c) Discussion to support why the evidence presented is sufficient to demonstrate that residual sterilant levels are within acceptable limits and do not adversely affect device safety or performance.
d) Validation protocols and full test reports (as per section B.3).

3.5.10 Animal Testing

The dossier shall contain information about any animal studies conducted to support the submission, including, where applicable, study protocols and full study reports. This shall include:

a) A summary of the non-clinical evidence that falls within this category, including study objectives, rationale for the animal model selected, study design, duration of study and follow-up period, endpoints, acceptance criteria and results.
b) A discussion of the non-clinical testing considered for the device and support for their selection or omission from the verification and validation studies conducted in this category (i.e., what tests were considered and why they were or were not performed), considering a risk-based approach and applicable standards.
    - The manufacturer shall include in the discussion the availability of alternative non-animal methods (e.g., in vitro, bench testing, literature data).
    - Prior clinical experience with similar devices or materials.
    - The manufacturer shall justify the need for animal testing where performed, or the adequacy of alternative evidence where animal testing was not conducted.
c) Discussion to support why the evidence presented is sufficient to demonstrate device safety and performance for the intended use.
d) Where applicable, the manufacturer shall confirm that animal studies were conducted in accordance with recognized ethical principles and applicable standards or regulations. including:
    - Approval by an institutional animal care and use committee (or equivalent).
    - Compliance with applicable national regulations.

- Adherence to internationally recognized ethical principles.
- Evidence of ethical approval and compliance shall be provided.

e) Full study protocols and reports as described in section B.3.

3.5.11 Usability/Human Factors

This section shall describe how use-related risks have been systematically identified, analysed, and controlled during device design and development. The manufacturer shall provide documentation demonstrating that usability and human factors have been addressed through a risk-based usability engineering process (e.g. IEC 62366-1), aligned with risk management (e.g. ISO 14971).

The submission shall include:

a) Summary of usability engineering process: overview of the usability engineering activities and key outcomes.
b) Intended users, environments, and use scenarios: identification of user groups (including e.g. competency, training, language and literacy requirements), use environments, expected use conditions, workflow constraints and resource limitations.
c) User interface, labelling, and IFU design: description of how the device interface and information for use were developed to support safe and effective use.
d) Use-related risk analysis: identification of use-related hazards, foreseeable use errors, and associated risks.
e) Critical tasks and risk control measures: identification of critical tasks and implementation of risk control measures.
f) Formative evaluations: description of usability evaluations conducted during development.
g) Scope and justification of testing: rationale for usability activities performed, demonstrating that user selection, test environments, use scenarios and acceptance criteria are representative of intended users and use context. Including the rationale for the omission of any usability studies, where applicable.
h) Environmental and contextual factors: consideration of environmental and contextual factors that may affect the device use (e.g. lighting, heat, humidity, workflow, maintenance, accessories, infrastructure).
i) Conclusion: demonstration that use-related risks have been appropriately identified and controlled through design.

Where usability is critical to safe use, or where the intended users include lay persons, **validation of usability shall be provided in Section 4.7.1**.

3.5.12 Evidence for devices with preservatives or antimicrobial claims

Applications for devices intended for multiple use or repeated access that contain a preservative system (e.g., lubricant), shall include evidence to support preservative efficacy.

a) The manufacturer shall also address potential interactions between the preservative system and packaging materials, device component and intended user population (e.g. sensitive tissues).
b) For devices that make antimicrobial or antimicrobial protection claims, evidence to support the antimicrobial efficacy relevant to the intended use shall be provided.
c) Such evidence shall include, where applicable,
    - Identification of the test methods used;
    - Reference to recognized standards;
    - Full study protocols and reports as applicable, in accordance with section B.3; and
    - Justification that the claimed preservative or antimicrobial function is effective and does not adversely affect device safety or performance.

3.5.13 Product specific studies (WHO prequalification specific heading)

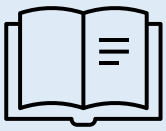
Specific requirements for non-clinical studies are found in the Technical Report series Annexes and Technical Specification series documents listed in Section D above. It is important that manufacturers refer to the documents relevant to their medical device when preparing their submission.

3.6 Non-clinical bibliography

This section shall include:

a) A listing of published non-clinical studies involving this specific device (e.g. cadaveric evaluations, biomechanical assessments).
b) Legible copies of key articles, including translation to English where applicable.
c) A discussion demonstrating the relevance and applicability of the published non-clinical data to the device under assessment and explaining how such evidence supports the demonstration of device safety and performance.

3.7 Expiration period and packaging validation



Specific stability study requirements are found in the Technical Report series Annexes and Technical Specification series documents listed in Section D above. It is important that manufacturers refer to these documents when preparing their submission.

A statement of the expiration period and the proposed storage conditions for the device (e.g., temperature, humidity, light exposure, pressure where relevant) when stored in its final packaging shall be provided in this section.

For devices that do not have an expiration period, information regarding the expected lifetime/service lifetime (i.e. the period of time the device is anticipated to safely meet its intended purpose) is required. Expected lifetime can be indicated as number of procedures to be performed with the devices/accessories as a period of time or other appropriate quantification.

3.7.1 Product stability

Details on the shelf-life testing conducted to support the claimed expiration date when stored under specified conditions and in final packaging configuration shall be submitted in this section.

- Determination of product shelf life shall be preceded by **simulated transport testing** using conditions representative of those likely to be encountered in resource-limited WHO Member States and with the product final packaging configuration.
- Claims for stability shall be based on documented real-time data from representative production lots. Where extrapolation is applied, the rationale and statistical methods used shall be described. Claims of shelf life from accelerated studies may be accepted as preliminary estimates, provided real-time studies are underway. The method used to estimate shelf life from accelerated data shall be provided.

- The product lots used in stability studies shall be equivalent to routine production and final packaging configuration. Product lots shall be in their final configuration, if the product is available in different configurations, testing shall be conducted on all configurations.

This section shall include the following information:

a) A statement of the expiration period/shelf life for each component and the proposed storage condition for the device (e.g., temperature, humidity, light exposure, pressure where relevant) when stored in its final packaging.
b) A description of the final packaging configuration used for stability testing.
c) A discussion of what tests were considered and why they were or were not performed.
d) Shelf-life study protocols (specifying the acceptance criteria, appropriate testing intervals and ensure that testing extends beyond the projected expiration date claim) and study reports as described in section B.3.
e) Where the device incorporates a medicinal substance or drug-device combination component, evidence supporting stability of the medicinal component at the proposed storage conditions shall be provided including absence of adverse interactions between the medicinal substance, device materials, and packaging components; and the chemical, physical, and microbiological stability of the medicinal component over the claimed shelf life.
f) Where applicable (e.g. lubricants), in-use stability study protocols and reports to support stability claims during actual routine use of the device (real or simulated) shall be provided. Simulated use studies shall be justified as representative of real-world conditions. The evaluation shall consider where applicable
    - Time between opening and use.
    - Duration of use after opening.
    - Repeated access (e.g. multi-dose containers, containers or dispensers).
    - Environmental conditions likely to be encountered during routine use.
g) Discussion demonstrating that the claimed shelf life and storage conditions are supported by appropriate stability data and that device safety and performance are maintained throughout the claimed period.

3.7.2 Packaging validation

The dossier shall contain details relating to package integrity over the claimed shelf life and under distribution conditions, and, where applicable, following exposure to sterilization processes. Transport/shipping stability evaluation shall reflect distribution conditions relevant to the intended markets, including environmental conditions likely to be encountered in resource-limited WHO Member States. Simulated transport/shipping studies shall be conducted prior to lots being placed on real time stability studies. As such the information below may be provided as part of the studies submitted in section heading 3.7.1. above.

- Where applicable, simulated transport/shipping studies (e.g., vibration, drop, climatic stress) shall be conducted in accordance with recognized standards to demonstrate that the critical device properties (such as device safety, performance, sterility (where applicable)) are maintained to ensure it will perform adequately and consistently during the entire proposed shelf life, and that the packaging integrity is maintained following distribution.

This section shall include the following information:

a) A description of the final packaging configuration and how it will maintain the devices sterility, bioburden or cleanliness.
b) If devices require special packaging (e.g. related to sterility, humidity, light, pressure), provide evidence that this has been addressed as part of the validation studies, and the internal environment has been maintained by the packaging during handling, transport and storage until the expiration date.

c) Provide evidence that the device in its final packaging configuration has undergone appropriate distribution/shipping simulation testing. Provide the shipping simulation study protocols and reports (including shipping simulation methodology and acceptance criteria) as described in section B.3.

4. Clinical evidence

Specific clinical study requirements may also be found in the Framework for clinical evaluation of devices for male circumcision, Technical Report series annexes, and Technical Specification series documents listed in Section D above. It is important that manufacturers refer to the documents relevant to their medical device when preparing their submission.

Clinical evidence is an important component of the technical documentation, which along with other design verification and validation documentation, device description, labelling, risk analysis and manufacturing information, is needed to allow a manufacturer to demonstrate conformity to the Essential Principles.

A manufacturer shall have sufficient clinical evidence to support all clinical claims and intended uses of the device.

4.2 Overall clinical evidence summary

Provide a brief (1-2 page) summary of the available clinical evidence being presented in support of the submission. The summary should provide the reviewer with a clear overview of the evidence supporting the safety, clinical performance, clinical benefit and intended use of the device under assessment. The summary shall:

a) List the evidence presented, its characteristics (RCT, case study, literature review, post market data from another jurisdiction or from a marketed device). A tabular listing of clinical studies may be included in this section;
b) Provide a discussion of the clinical evidence considered for the device and support for their selection (i.e., what type of evidence was considered and why they were or were not used);
c) Provide a discussion demonstrating that the totality of the clinical evidence is sufficient to support the safety, clinical performance, clinical benefit and intended use of the device. In particular, the manufacturer shall demonstrate that:
    - The evidence addresses all intended uses and clinical claims;
    - The target population is adequately represented;
    - Performance outcomes are clinically meaningful;
    - Identified risks are characterized and acceptable; and
    - The overall benefit–risk determination is favourable.
d) Where clinical evidence is based, fully or partly, on data generated with another medical device or with a previous generation of the device, equivalence shall be justified with regard to the relevant clinical, technical and biological characteristics. This shall include a detailed comparison of the clinical, technical, and biological characteristics of the two devices, with a detailed critical analysis demonstrating that the differences do not adversely impact the validity of the clinical evidence in support of the application. Refer also to Appendix A of the IMDRF document MDCE WG/N56FINAL:2019 entitled “Clinical Evaluation”.[10] The following information shall be provided:

[10] As amended from time to time

- Clinical characteristics shall include, as applicable, the intended purpose and intended use of the device, the clinical condition or purpose addressed, the severity and stage of the disease or condition, the intended patient population, including geographical or epidemiological specificities where relevant, the intended users, the use environment and the conditions of use;
- Technical characteristics shall include, as applicable, the device design, specifications, physicochemical properties, principles of operation, software and algorithmic characteristics, including alerts, alarms or outputs generated by the device, critical performance requirements related to the medical purpose, accessories or devices intended to be used in combination, and the relevant conditions of use;
- Biological characteristics shall include, as applicable, the materials or substances in direct or indirect contact with the same human tissues or body fluids, the type and duration of contact, biocompatibility considerations, and relevant release characteristics of substances, including degradation products and leachables; and
- Any identified difference shall be assessed with regard to its potential impact on safety, clinical performance and/or effectiveness. Where differences exist, the applicant shall provide a rationale, supported by appropriate evidence, demonstrating that these differences do not result in a clinically meaningful difference between the devices.

Note: For Human factors testing, refer to section heading 4.7 below.

4.2.1 Clinical evaluation report

a) Provide a clinical evaluation report reviewed and signed by expert(s) with appropriate qualifications and documented expertise in the relevant field that contains an objective critical evaluation of all the clinical data submitted in relation to the device.
b) A complete curriculum vitae, or similar documentation, demonstrating the qualifications and experience and justifying the manufacturer's selection of the clinical expert(s) shall be included in the submission.

4.2.2 Device specific clinical trials

All claims for the clinical performance of the product shall be supported by well-designed clinical investigations. If no clinical performance investigations are deemed necessary, this shall be explained and justified by the manufacturer.

In addition to the information described in section B.3, clinical studies provided in this section shall include:

a) A detailed written study plan and protocol explaining the objectives, study design (including study population, inclusion and exclusion criteria, study procedures, comparator or reference standard- where applicable), endpoints, and overall study methodology.
b) The date/s on which the study was performed and identification of study site(s).
c) All abbreviations used in reports and on data records shall be defined and spelt out in full.
d) A written report on the outcome of study. This report shall explain how the study results support the product clinical claims. Any anomalous results, or results that are not within predetermined specifications, shall be clearly explained or justified.
e) Clear identification of the product and product version that is being evaluated.
f) Details of the product lots/batches used for the evaluation, including lot number, date of expiry, and the storage conditions of the product prior to and during the study.
g) Details of the geographical region and the clinical status of the subjects included in the study.
h) Full details of the methods used to define the clinical status of the subjects.
i) Full details of statistical methods, estimations and calculations applied.
j) Actual test results and their acceptance criteria shall be provided and not just pass/fail statements. All data provided shall be clearly labelled and shall be clearly linked to the study report.
k) Any deviations, adverse events, or unexpected outcomes shall be clearly described and evaluated.

l) Where quantitative endpoints are used, appropriate statistical measures and confidence intervals shall be provided. All enrolled subjects and outcomes shall be accounted for and appropriately analysed.
m) Evidence that the outcomes of the clinical investigation have been reviewed by the manufacturer and formally accepted.
n) If the study has been published in peer-reviewed scientific literature, provide publication details for the study.
o) Testimonials from hospitals, laboratory staff, product users, or patients are not considered clinical evidence and shall not be included in the dossier.

4.2.2.2 Specific clinical trial requirements for male circumcision devices ***(WHO prequalification specific heading)***

WHO prequalification specific content: The WHO Technical Advisory Group on Innovations in Male Circumcision has recommended that the following pivotal clinical studies shall be conducted independently from the manufacturer in at least two countries representative of the intended use setting: data from at least one randomized controlled trial that compares the performance of the device with standard procedures (currently surgical), and at least one non-comparative field study in settings of intended use shall be required for review.

a) Clinical study _ Phase 1 (randomized controlled trial):

This phase includes a comparative study (at least 100 patients) that compares the performance of the device with a standard surgical procedure in a randomized controlled trial. This trial needs to be performed by surgeons skilled and equipped to offer either method.

b) Clinical study _ Phase 2 (field study):

This study phase also called field study, is a non-comparative field trial of the device in settings of intended use, with procedures performed by trained mid-level providers (non-physicians). A cohort study of at least 500 patients in each country is enrolled and followed up.

It is anticipated that principal investigators responsible for the independent clinical trials and field studies will provide a detailed full study protocol, the method of data analysis and the full study report directly to WHO (WHO Department for HIV, TB, Hepatitis, and Sexually Transmitted Infections (HTH)). This information will be reviewed by experts and presented to the WHO Technical Advisory Group on Innovations in Male Circumcision (TAG IMC) for their review. The recommendation from the TAG IMC will constitute the information required for this section of the dossier.

Scientifically sound clinical data shall include:

- The evaluation study design, study protocol, results, and conclusions;
- The date/s on which the study was performed;
- Clear identification of the product and product version that is being evaluated;
- Details of the product lots/batches used for the evaluation, including lot number, date of expiry, and the storage conditions of the product prior to and during the study;
- Details of the geographical region and the clinical status of the subjects included in the study;
- Details of the methods used to define the clinical status of the subjects;
- Details of statistical methods, estimations and calculations applied;
- Details of the entity which performed the evaluation, including current contact details; and
- A declaration from the entity which performed the evaluation declaring any interests that could constitute a real, potential, or apparent conflict of interest with respect to their involvement in the independent study of this product or the manufacturer of the product.

4.2.3 Clinical literature review and other reasonable known information

The manufacturer shall provide a structured clinical literature review demonstrating that all relevant clinical data have been systematically identified, appraised, and analysed to support the safety, performance, and intended use of the device. This shall incorporate:

a) A documented search protocol to a level of detail that allows the search to be reproduced.
b) Defined and justified inclusion and exclusion criteria used for study selection.
c) Criteria for appraising the data (both favourable and unfavourable) to determine the contribution of each data set to support the conclusions.
d) Results of the literature search.
e) A description of the relevance of the identified literature to the device under assessment, its intended use, and target population.
f) Where literature relates to equivalent or comparable devices, then the following shall be described:
    - A clear identification of the referenced device(s).
    - A structured comparison of clinical, technical, and biological characteristics (as applicable – see information requirements in chapter heading 4.2 above).
    - Justification that the data are applicable to the subject device.
g) A critical analysis synthesizing the totality of the evidence and explaining how it supports the device's safety, clinical performance and benefit–risk profile.
h) Identification and discussion of any contradictory findings, safety signals, or limitations in the literature, and their impact on the overall clinical evaluation.
i) A legible copy of the key articles.
j) Or a statement that no literature related to the device was found.

4.7 Other Clinical Evidence

*4.7.1 Qualification of usability (**WHO prequalification specific heading)***

WHO prequalification specific content: Where the intended users include lay persons, or where usability is critical to the safe and effective use of the device, the manufacturer shall provide objective validation evidence demonstrating that the device can be used safely and effectively by representative users under conditions reflecting the intended use environment.

Detailed information on the usability engineering process, including identification of intended users, use environments, use-related risk analysis, critical tasks, and risk control measures, is provided in **Section 3.05.11 (Usability/Human Factors)**.

Usability validation shall be conducted in accordance with recognised usability engineering principles (e.g. IEC 62366-1) and integrated with the overall risk management process (e.g. ISO 14971). The manufacturer shall justify that the users, environments and use scenarios selected for usability validation are representative of the intended WHO prequalification context, including the expected end users, level of training, language and literacy needs, workflow, infrastructure and resource constraints in the countries and settings where the device is intended to be used.

The submission shall include:

a) User population and use environment: Description of representative users and use environments reflecting intended use.
b) Validation methodology and acceptance criteria: Summary of study design, test conditions, and predefined acceptance criteria.

c) Validation of critical tasks: Evidence that all critical tasks identified in Section 3.05.11 have been evaluated under representative use conditions.
d) Results from representative user testing: Outcomes of usability validation studies conducted with representative users.
e) Use error evaluation: Assessment of observed use errors and whether these result in unacceptable risk.
f) Confirmation of risk control effectiveness: Demonstration that risk control measures identified in Section 3.05.11 adequately reduce use-related risks.
g) Conclusion: Confirmation that the device can be used safely and effectively, and that residual use-related risks are acceptable within the overall benefit–risk determination.

Where usability validation is not conducted, the manufacturer shall provide a documented justification, based on the device design, intended use, and risk profile.

5. Labelling and promotional material

Specific requirements for labelling are described in the Technical Report series Annexes and Technical Specification series documents listed in Section D above. It is important that manufacturers refer to the documents relevant to their medical device when preparing their submission.

The purpose of labelling is to identify the medical device and its manufacturer and provide essential information about its safety, performance and appropriate use to the user or other relevant persons. Such information may appear on the device itself, on packaging, or as instructions for use. These documents should be developed and evaluated using risk management principles and usability engineering processes.

- The intended use claim must be clearly stated in the device labelling. All implied claims made elsewhere in the labelling must be consistent with the official statement.

5.2 Product/package labels

In this section, the manufacturer shall provide all packaging labels used in the product. This includes primary and secondary labelling of all devices, accessories and components (but exclusive of labels for shipping). The labelling shall include at a minimum the information as outlined in the IMDRF GRRP WG N52 document *"Principles of Labeling for Medical Devices and IVD Medical Devices"* [11].

5.3 Package insert/instructions for use

In this section, the manufacturer shall provide the current product IFU. The information provided in a product IFU shall be clear, correct, suitable for intended users and consistent with that provided in the product dossier. The IFU shall include at a minimum the information as outlined in the IMDRF GRRP WG N52 document *"Principles of Labeling for Medical Devices and IVD Medical Devices".* [12]

- The current version and date of the instructions for use must be stated.

5.4 e-labelling

In this section, the manufacturer shall provide e-labelling and in addition, the following:

[11] As amended from time to time
[12] As amended from time to time

a) For eligible medical devices and Software as a Medical Device, identify which form of e-labelling is being used (e.g. electronic storage system or built-in system, website).
b) Provide details of risk management in relation to e-labelling. If this is part of the overall risk management, reference should be made to the applicable section where it has been provided.
c) When IFUs are requested, a description of the procedure and operations on providing IFU's when requested.
d) Written information for users on the webpage identifying where the IFU and further information can be found in relevant languages.
e) A description on how the e-labelling requirements for the website have been met.
f) If a video/app is available to demonstrate how the device is intended to function, provide a link as well as details about how it is maintained and updated throughout the life cycle of the device.

5.5 Healthcare professional labelling

In this section, the manufacturer shall provide labelling that is directed at the healthcare professional other than the package insert.

5.6 Patient labelling

In this section, the manufacturer shall provide labelling that is directed at the patient other than the package insert, such as informational material written to be comprehended by the patient or lay caregiver.

5.7 Technical and/or operators manual

If the device requires associated instrumentation, software, or dedicated accessories, the manufacturer shall include copies of the relevant technical manuals and/or operator manuals focusing on proper use and maintenance of the device, and surgical technique instruction. Where applicable, configuration manuals, service manuals, or software user guides shall also be provided.

5.10 Other labelling and promotional material

Provide copies of any other labelling other than those described above, including advertising and promotional material.

6. Quality management system

The quality management system of the manufacturer will be assessed as part of the manufacturing site inspection which is a separate prequalification assessment component.

6.12 Production and service controls

The manufacturer shall provide the following product-specific manufacturing process relevant documentation:

a) Identification of all manufacturing sites.
b) A manufacturing process flow diagram identifying major manufacturing steps, critical manufacturing processes (e.g., assembly sterilization, packaging, etc.), and which includes the key quality control points (in-coming verification, in-process, release etc.,). If multiple facilities/sites are involved in the manufacture, the applicable information for each site shall be submitted.
c) Batch release criteria for the product and the certificate of analysis of the three most recent lots if applicable.
d) List of critical materials, components, and subassemblies that may affect device safety, performance, quality.

e) List of critical suppliers and subcontractors involved in the manufacture, sterilization, testing, packaging, storage, release of the device, or other processes. Provide their role, location, relevant certifications, and where applicable relevant accreditations and/or regulatory approvals.
f) List the outsourced special processes, where applicable (e.g. sterilization, coating, biological processing, packaging validation, or other validated manufacturing activities).
g) Where service activities are not applicable to the device, no additional information regarding service controls is required.

Note: For software medical devices and devices incorporating software, including artificial intelligence or machine learning technologies, the information provided in this section shall focus on software build, release, deployment, configuration management, and associated quality controls, as applicable. Detailed software lifecycle documentation, including software development, verification, validation, maintenance, and release management processes, shall be provided in Section 3.5.5.

End of Dossier content

F. Contact information

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

Annex 1 – Abridged product dossier requirements

The following sections and subheadings are required to be submitted as part of an abridged product dossier. Please note the following:

- The instructions outlining the submission requirements for each section listed below is described in section E "Dossier content" of this document.
- Not all sections and subheadings in the instructions below will be applicable to every submission, and manufacturers are required to provide only the information relevant to their device. Where a section is deemed not applicable, the manufacturer shall provide a documented justification within the product dossier.

Section 1. Regional administrative

1.1 Letter of agreement (WHO prequalification specific heading)
1.2 Product dossier checklist (WHO prequalification specific heading)
1.3 List of terms/acronyms
1.4 Application form/administrative information
1.5 Listing of device(s)
1.6 Quality management system (QMS), full quality system or other regulatory certificate
1.7 Free sale certificate/certificate of marketing authorization
1.12 Statements/certifications/declarations of conformity
1.12.5 Truthful and accurate statement
1.12.7 Declaration of conformity

Section 2. Submission context

2.4 Device description
2.4.1 Comprehensive device description and principle of operation
2.4.2 Description of device packaging
2.5 Indications for use and/or intended use
2.5.1 Intended use; Intended Purpose; Intended User; Indications for Use
2.5.2 Intended environment/setting for use
2.5.4 Contraindications For Use

2.6 Global market history
2.6.1 Global market history
2.8 Risk management
2.9 Essential Principles (EP) checklist
2.10 Standards
2.10.1 List of standards and guidance documents

2.11 Other submission context information
2.11.1 Training and support networks (WHO prequalification specific heading)

Section 3. Non-clinical evidence

3.5 Non-clinical studies
3.5.5.4 System and Software Architecture Design (SAD) Chart
3.5.5.8 Software Testing as Part of Verification and Validation
3.5.6 Biocompatibility and Toxicology Evaluation
3.7 Expiration period and packaging validation
3.7.1 Product stability
3.7.2 Packaging validation

Section 4. Clinical evidence

4.2 Overall clinical evidence summary
*4.2.1 Clinical evaluation report *Please include where clinical studies are required to support the clinical safety, performance, or intended use of the device, including where specified by applicable WHO guidance and specifications listed in section D.*

4.2.2.2 Specific clinical trial requirements for male circumcision devices (WHO prequalification specific heading)

4.7 Other Clinical Evidence

4.7.1 Qualification of usability (WHO prequalification specific heading)

Section 5. Labelling and promotional material

5.2 Product/package labels
5.3 Package insert/instructions for use
5.4 e-labelling
5.5 Healthcare professional labelling
5.6 Patient labelling
5.7 Technical and/or operators manual
5.10 Other labelling and promotional material