Reportable changes to WHO prequalified and emergency use listed IVD & non-IVD Medical Devices Guidance

Reportable changes to WHO prequalified and emergency use listed in vitro diagnostic & non-in vitro diagnostic medical devices

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Abbreviations

EUL	emergency use listing
ISO	International Organization for Standardization
IVD	in vitro diagnostic medical device
PQ	prequalification
QMS	quality management system
RRA	recognized regulatory authority
SOP	standard operating procedure
WHO	World Health Organization
WHOPAR	WHO's public assessment report
WHOPIR	WHO's public inspection report

For the purposes of this document, the acronym **"IVD"** refers to an **in vitro diagnostic medical device**, **"MD"** refers to a **non-in vitro diagnostic medical device**, and **"devices"** refers collectively to both IVDs and MDs.

1. Purpose of this document

This PQDx_121 guidance establishes one risk-based process for identifying, categorizing, documenting and submitting changes to WHO prequalified and EUL listed in vitro diagnostic (IVDs), and non-IVD medical devices (MDs). This guidance applies to WHO prequalified and EUL medical devices, unless otherwise specified.

This document provides guidance on submission and WHO Change Requests' decision process and is designed to be used together with document PQDx_119 form. The change request form captures the information necessary for WHO to make an informed assessment, it covers rationale and evidence in a consistent submission format.

The objectives are to maintain the validity of WHO prequalification/EUL listing, protect continued device quality, safety and performance, support transparent and proportionate review, and ensure that public and regulatory information remains current.

Where specific requirements apply only to IVDs or only to MDs, these are explicitly identified as such.

This document supersedes "Reportable changes to WHO prequalified and emergency use listed in vitro diagnostics: application guidance" v1 published in 2025 (also referred to as PQDx_121) and "Reportable changes to a WHO Prequalified Male Circumcision Device (also referred to as PQMC_121 v1) published in 2019. This revised version expands the scope of the guidance to include non-in vitro diagnostic medical devices. It also includes feedback received through the 2025 survey of manufacturers of WHO-prequalified IVDs, as well as lessons learned from the implementation of the previous guidance.

2. Scope and audience

This guidance applies to legal manufacturers of WHO prequalified and EUL IVDs and MDs or their authorized personnel. It covers changes to the device, intended use, design, materials and accessories, components,

software, manufacturing and quality-control processes, sites and suppliers, sterilization, packaging, stability, labelling, traceability, regulatory status, and the quality management system (QMS).

It applies after prequalification and before the release of a changed product or a product manufactured under changed conditions. It does not replace the manufacturer's change control, or design-change control, software-lifecycle, risk management or QMS obligations.

Product-specific examples of changes are provided in Annex 1 for IVDs, and Annex 2 for MDs such as, condoms, intrauterine devices (IUDs) and computer-aided detection software for tuberculosis (CAD-TB) and male circumcision devices. The examples are illustrative and do not override the risk-based assessment of the actual change.

3. Definitions and terms

3.1 Definitions

Clinical Evaluation Report (CER)	Documented assessment and analysis of clinical data demonstrating the safety, performance and benefit-risk profile of a medical device throughout its lifecycle.
Implementation	Release to the market of the changed device or devices manufactured under the changed conditions.
Low-impact reportable change*	A reportable change with low potential to affect the quality, safety, performance, usability or intended function of a prequalified/EUL device, or that requires an update to WHO records, WHO-assessed documentation or public information, while requiring only limited technical assessment.
Manufacturer	Any person or legal entity who makes a finished device available under their own name, regardless of whether they perform these operations themselves or have a third party do it on their behalf. This includes entities performing assembly, packaging, processing, or labelling of finished products. Anyone who modifies a device's intended use or alters a finished device under their own name is also classified as a manufacturer. [**1**]
Moderate/High-impact reportable change*	A reportable change with the potential to significantly affect the quality, safety, performance, usability or intended function of a prequalified/EUL device and that may require a higher level of assessment and supporting evidence to demonstrate continued conformity with applicable requirements.
New Prequalification (PQ) application change	A change that creates a device materially different from the prequalified device such that continued coverage by the existing prequalification cannot be established through a change request.
Non-reportable change	A change demonstrated through documented impact and risk assessment to have no potential effect on the device quality, safety, performance, usability, cybersecurity or intended use or its approved information and not otherwise identified by this guidance as reportable.
Post-Market Clinical Follow-up (PMCF)	Continuous process to update the clinical evaluation through collection and assessment of clinical data obtained from use of the device after-market placement.

Regulatory Reliance	"The act whereby the regulatory authority in one jurisdiction takes into account and gives significant weight to assessments performed by another regulatory authority or trusted institution, or to any other authoritative information in reaching its own decision." [**2**]
Regulatory version	Refers to and relates to all the information and documentation associated with a submission for acceptance of a product by a regulatory authority including, without limitation, all documentation related to development, manufacture, intended use, labelling and post-market surveillance of the product, as well as all documented evidence supporting the safety and performance claims associated with that submission. In the event that (i) regulatory versions of a product have been submitted to different regulatory authorities or designated notified bodies (e.g., United States Food and Drug Administration, Health Canada, a Notified Body for CE marking, etc.) and (ii) any aspect of the documentation or information associated with such submitted regulatory versions differs in any way, then the submitted regulatory versions are considered to be a different regulatory version.
Reportable change	A change with the potential to affect the quality, safety, performance, usability, cybersecurity, intended use or benefit-risk profile of the prequalified/EUL device, and which requires additional technical evidence to demonstrate continued conformity.
Unique Device Identification (UDI)	A series of numeric or alphanumeric characters created through a globally accepted device identification and coding standard that allows unambiguous identification of a specific device.

* The potential impact category shall be determined not only by the potential effect of the change on quality, safety and performance, but also by the extent of new evidence required to demonstrate continued conformity of the device.

3.2 Terms

- The manufacturer remains responsible for change control, impact assessment, risk management, verification, validation, acceptance, traceability, and the appropriate implementation of any change.
- All changes must be managed in accordance with the manufacturer's approved internal change control procedures.
- Reportability is determined by the change potential impact and by the need to update WHO-approved or public information.
- Multiple changes that are individually considered minor or limited may have a cumulative impact that warrants reclassification of the change category or, where applicable, may be significant enough to require consideration as a new product.
- The same change shall be assessed across the entire affected product family, including configurations, accessories, sites, software versions and markets covered by WHO prequalification.
- When doubt remains, the manufacturer should consult WHO before implementation.

4. Determining whether a change is reportable

4.1 Decision sequence

1. Define the change precisely: current state, proposed state, reason, scope, affected product codes/versions/sites and planned implementation date.
2. Identify all affected prequalification information, including the dossier, WHOPAR, WHOPIR, labelling, QMS and reliance information.
3. Identify whether the proposed change affects information, processes, sites, responsibilities or controls previously reviewed by WHO during a manufacturing-site inspection, or in the manufacturer's commitments to WHO or corrective actions arising from previous evaluations or inspections.
4. Evaluate direct, indirect and cumulative effects on quality, safety, performance of the product, including, as applicable, its design, manufacture, usability, software/cybersecurity, clinical or analytical performance and evidence, and overall benefit-risk profile. Determine whether the changed product remains within the identity and scope of the existing prequalification.
5. Classify the change as non-reportable, Low impact, Moderate/High impact, or requiring a new PQ application.
6. Document the decision in the QMS and, when reportable, complete PQDx_119 form and attach the mapped evidence.

4.2 Non-reportable changes

A change may be managed without prior submission only when the manufacturer documents that it has no potential impact on the device or approved/public information, is not listed as reportable, and does not form part of a related set of changes with reportable cumulative impact. The decision and evidence shall be retained in the QMS.

The manufacturer's classification and justification of a change as non-reportable shall be retained within the QMS and made available to WHO upon request. The adequacy of the decision, the supporting records and the implementation of the change may be reviewed during routine or risk-based post-prequalification inspections.

- Editorial corrections to internal procedures with no effect on product or process requirements.
- Like-for-like replacement of calibrated equipment using the same validated principle, specifications and controls.
- Routine maintenance of validated infrastructure or IT systems with no effect on process control, data integrity, cybersecurity or device performance.
- Internal organizational changes that do not change quality, regulatory, design, manufacturing, release or vigilance responsibilities.

4.3 Reportable changes

A change is reportable when any reasonable pathway exists by which it could affect an approved characteristic or risk, when additional verification or validation is required to establish continued conformity, or when WHO records or WHOPAR must be updated. Reportable changes require WHO approval before implementation unless WHO explicitly indicates otherwise.

The change request form and supporting documentation will be subject to a desk review before WHO approves the change. Any reportable change, including a change already accepted by WHO, may subsequently be reviewed and verified during post-prequalification monitoring activities, including periodic or risk-based inspections.

Note: The absence of a specific example in this guidance or its annexes does not imply that a change is non-reportable.

4.4 Changes that may require a new PQ application

A new PQ application is generally required when the proposed changes result in a device that can no longer be demonstrated to remain within the identity, intended use, technology and benefit-risk profile of the currently prequalified/EUL device. In such cases, the manufacturer should seek advice from WHO to determine whether a new prequalification or EUL application is required.

Please refer to Annex 5.

5. Determining the potential impact of a reportable change

Determining the potential impact of a reportable change is an important step in the change-management process. It guides the manufacturer in identifying the information and supporting documentation to be submitted with the reportable change request and informs WHO's decision on the level of assessment required.

The manufacturer shall classify each reportable change as either:

a) Low-impact reportable change; or

b) Moderate/High-impact reportable change.

The classification shall be based on the nature and extent of the proposed change, the associated hazards and risks, and its potential impact on the quality, safety, performance, usability, cybersecurity or intended use of the WHO prequalified/EUL IVD or MD.

The change shall be assessed within the context of the prequalified product, including all affected product codes, configurations, accessories, software versions, manufacturing sites and suppliers. Related or simultaneous changes shall be considered together when determining their cumulative impact.

5.1 Factors to be considered

When determining the potential impact of a reportable change, the manufacturer shall consider the following, as applicable:

Product design, composition and performance

The manufacturer shall consider:

- changes to the design, composition, formulation, dimensions, configuration, operating principle or functional characteristics of the product;
- redevelopment activities, including technological updates and improvements reflecting the current state of the art;
- changes to the attributes, specifications or sources of critical materials, components, parts, reagents, accessories or reference materials;
- changes to analytical, clinical, mechanical, biological or other performance characteristics; and
- changes introducing new safety, performance, usability or clinical considerations that may require additional verification, validation, or clinical or performance evidence.

Intended use and information provided with the product

The manufacturer shall consider:

- changes to the intended use, indications for use, target condition, target population, intended user, operating environment or procedure for use;
- changes to the product or its accessories that may affect continued conformity with the applicable Essential Principles of Safety and Performance of Medical Devices and IVD Medical Devices; and
- changes that may affect compliance with applicable Technical Specifications Series (TSS) documents, other applicable WHO technical specifications, or previously submitted technical documentation.

Software, cybersecurity and interoperability

The manufacturer shall consider:

- changes to software elements, algorithms, calculation methods, interpretation logic or software architecture;
- changes to software-lifecycle documentation, development or release environments;
- changes to interoperability, connectivity or data integrity; and
- changes to cybersecurity risks, controls, authentication, access management, system availability or security architecture.

Manufacturing, QMS and supply chain

The manufacturer shall consider:

- changes to manufacturing processes, technologies, facilities, equipment, environmental controls, sterilization processes or packaging systems;
- changes to manufacturing, quality-control, testing, calibration, release, storage, transport or distribution activities;
- changes to the organization of the manufacturer or to the responsibilities or activities of critical suppliers, subcontractors or service providers;
- changes to materials, manufacturing processes or disposal requirements that may affect environmental safety or compliance with requirements applicable to hazardous substances; and
- changes that may affect the continued compliance of the manufacturing site or QMS with applicable standards and WHO prequalification requirements.

Regulatory, prequalification and inspection information

The manufacturer shall consider:

- changes that may affect an authorization, certification, classification or regulatory decision in another jurisdiction and may influence continued compliance with WHO prequalification requirements;
- changes that alter information previously submitted to or assessed by WHO, including information relating to the product dossier, manufacturing site, QMS, performance evaluation, clinical evidence, or manufacturing-site inspection;
- changes that may affect an inspection conclusion, an agreed corrective action, a manufacturer commitment or information included in the WHOPIR; and

- changes requiring an update to WHO-approved information, public information, the WHOPAR, the WHOPIR or the list of prequalified products.

This list is not exhaustive. The manufacturer shall consider any other product-, process-, site- or QMS-specific factor that could affect the continued quality, safety, performance or regulatory compliance and overall benefit-risk balance of the prequalified product.

5.2 Impact on risk management and benefit-risk determination

The manufacturer shall evaluate the potential effect of the proposed change on the overall residual benefit-risk determination in accordance with ISO 14971 [**3**] or equivalent risk-management principles.

The manufacturer shall evaluate the potential effect of the proposed change on the continued conformity, suitability and effectiveness of the quality management system in accordance with ISO 13485 [**4**] or equivalent quality management principles.

The manufacturer shall demonstrate that the Risk Management File has been reviewed and updated where applicable and that the overall benefit-risk determination remains acceptable following implementation of the change.

This evaluation shall determine whether implementation of the change could:

- introduce a new hazard or hazardous situation that was not previously identified;
- introduce a new sequence of events leading to a hazardous situation;4
- increase the probability of occurrence or severity of harm associated with an existing hazard;
- change the effectiveness of an existing risk-control measure;
- require a new or modified risk-control measure;
- create a new risk as a result of implementing a risk-control measure;
- affect the acceptability of individual residual risks or the overall residual risk;
- alter the expected benefits of the product or the overall benefit-risk determination;
- affect information for safety, including warnings, precautions, contraindications, limitations, operating instructions or training requirements;
- alter information previously submitted during the WHO prequalification or Emergency Use Listing assessment, including information relating to the product dossier, manufacturing sites, inspections, performance evaluation, software, usability, labelling or compliance with the applicable Essential Principles; or
- affect the continued compliance of the manufacturer's QMS with applicable standards and WHO prequalification requirements.

The impact assessment shall consider both the direct effects of the change and any indirect or cumulative effects arising from related changes.

5.3 Assignment of the potential impact category

Once a manufacturer has determined that a change is reportable in accordance with the principles and criteria described in the preceding sections, the manufacturer shall then determine the appropriate potential impact category of the change.

A change may be reportable while requiring only limited assessment by WHO where the potential impact remains low. Conversely, a reportable change may require more detailed review where significant evidence is necessary to demonstrate continued conformity with applicable requirements.

Low potential impact change

A reportable change should generally be classified as Low potential impact when the manufacturer demonstrates that:

- the change does not introduce a new hazard or hazardous situation;
- the change does not meaningfully increase an existing risk;
- the intended use, operating principle and principal performance claims remain unchanged;
- the change does not require substantial new verification, validation, clinical or performance evidence;
- continued conformity can be demonstrated using existing documentation or focused supporting evidence; and
- the change primarily requires verification of the categorization or an update to WHO records or public information.

Moderate/High potential impact Change

A reportable change should generally be classified as Moderate/High impact when it:

- introduces a new hazard or hazardous situation;
- may increase the probability or severity of harm;
- changes a risk-control measure or the overall benefit-risk determination;
- may affect the intended use, operating principle, design, safety, performance, usability, cybersecurity or clinical use of the product;
- affects a critical material, component, process, supplier, manufacturing site, sterilization process, software function or quality-control activity;
- requires substantial verification, validation, clinical, performance, stability, biocompatibility, sterilization, usability, software or process-validation evidence; or
- creates significant uncertainty regarding the continued quality, safety or performance of the prequalified product.

Where several changes are submitted together, the overall submission shall be assigned the highest impact category applicable to any individual change or to their cumulative effect. Please also refer to **section 6.3** of this document.

If the proposed change would result in a product that is substantially different from the prequalified/EUL product, the manufacturer should seek advice from WHO to determine whether a new prequalification or EUL application is required. Please also refer to **section 4.4** of this document.

5.4 Documentation supporting the impact assessment

The manufacturer is not expected to create a separate set of records solely for the WHO reportable change request. The impact categorization should be supported by documentation generated through the manufacturer's established QMS and internal change-management processes.

This may include, as applicable:

- the approved change-control record;
- a comparison of the current and proposed states;
- the impact assessment;
- updated risk-management documentation;
- design or process verification and validation records;
- analytical, clinical, mechanical or software performance evidence;
- stability, packaging, sterilization or biocompatibility evidence;
- usability and cybersecurity assessments;
- supplier, manufacturing-site or QMS documentation;
- updated labelling, IFU and other public information; and
- the manufacturer's approval and implementation records.

The information supporting the proposed impact category shall be summarized and cross-referenced in PQDx_119 form.

Annexes 1 and 2 provide non-exhaustive examples of reportable changes and their indicative impact categories for different product types. They also identify the supporting evidence that may be expected for Low-impact and Moderate/High-impact changes.

The examples do not replace the manufacturer's assessment of the actual change. Each change shall be evaluated within its specific context, and the manufacturer remains responsible for determining and justifying the proposed impact category.

5.5 WHO verification of the proposed potential impact category

WHO will verify the manufacturer's proposed potential impact category as part of the initial completeness and categorization check.

If WHO agrees with the proposed category, the change request will proceed through the applicable assessment pathway.

If WHO does not agree with the proposed category, WHO will inform the manufacturer and may reclassify the change:

- Where a change is reclassified as potential Low potential impact, WHO will conduct the applicable completeness and categorization check. A full technical assessment will generally not be conducted unless specific concerns require further review.
- Where a change is reclassified as potential Moderate/High impact, WHO may request the additional information and supporting documentation necessary to conduct a full assessment. **Where eligibility criteria are met, an abridged assessment may be considered.**

WHO may also determine that the proposed change falls outside the scope of the existing prequalification/EUL and requires a new application.

The WHO assessment pathways and possible outcomes are described in Section 7 of this guidance.

Please also refer to Annex 5.

6. Preparing a reportable change application using PQDx_119

The application shall follow the sequence and terminology of PQDx_119 form. Information should be entered once in the form and cross-referenced to clearly named attachments. The following alignment is mandatory for complete submission. As part of the application please complete the questionnaire provided in Annex 4. (Manufacturer decision checklist).

PQDx_119 section	Guidance for the compilation of a complete submission
2. Manufacturer declaration	Confirm the accuracy and completeness of the submission, disclosure of linked and cumulative changes, availability of supporting evidence, and compliance with applicable WHO requirements for implementation and market release. Provide the name, title, signature and date of the duly authorized representative.
3. Product and submission identification	Provide the product name and PQ number(s), affected models/configurations and product codes, legal manufacturer and contact details, submission date, manufacturer change-control reference, and any related WHO submissions, CAPA, recalls or previous change requests.
4. Description and scope of the change	Clearly describe the current approved state, proposed state, reason/trigger, scope and boundaries of the change, affected products, sites, markets and versions, linked or cumulative changes, and proposed implementation milestones. Each distinct modification should be identified and traceable to supporting documentation.
5. Categorization & potential impact assessment	State the proposed potential impact category and provide the reportability and categorization rationale in accordance with this guidance. Assess the potential impact on relevant aspects of the product, including intended use, quality, safety, performance, benefit risk, design, software, usability, cybersecurity, manufacturing and QMS, as applicable. Address whether the change may require a new PQ application.
6. Core supporting evidence	Provide evidence proportionate to the nature and impact of the change, including the change-control record, risk assessment, before/after comparison, verification and validation evidence, cumulative-change assessment, updated labelling or WHO public information where applicable, PMS/vigilance impact, and supporting controlled documents.
7. Recognized-authority/abridged-assessment information	Complete only when an applicable reliance or abridged-assessment pathway is requested. Identify the recognized authority, product/version and exact change assessed, decision status and dates, supporting assessment evidence, and any differences or exclusions. Demonstrate that the change and supporting evidence correspond to those assessed by the recognized authority.
8. Administrative information and public documents	Identify any required changes to manufacturer or product information, labelling, IFU, packaging, WHOPAR or other WHO public information. Provide clean and redlined versions where applicable and justify administrative-only changes as having no technical impact.
9. Technical and QMS evidence modules	Complete the evidence modules applicable to the nature of the change and product type. Address relevant QMS/manufacturing, suppliers, design, safety and performance evidence and complete the applicable **IVD-specific** or **MD-specific** module. Non-applicable items should be identified and justified.
10. Implementation, transition and post-market plan	Describe implementation and transition arrangements, controls preventing unauthorized manufacture/release where applicable, post-implementation verification, PMS and vigilance activities, corrective-action readiness, support obligations, and arrangements for reporting material deviations or new risks to WHO.

11. Request to withdraw a product from PQ/EUL listing	Complete only if the manufacturer is requesting to remove a product from WHO prequalification/EUL listing. Provide the reason, proposed effective date, cessation and residual-stock arrangements, affected markets, continuity considerations, PMS/vigilance obligations and closure arrangements.
12. Annex index and final submission check	Identify all submitted annexes using controlled document titles, identifiers and versions, and verify the completeness and consistency of the submission before signature and submission to WHO.

6.1 Change description

Provide a clear comparison (refer to PQDx_119 form) between the currently prequalified/EUL product and the product incorporating the proposed changes, identifying all relevant differences. Avoid statements such as "minor update" without technical detail. Identify every affected product code, component, site, specification, document and software version. Explain the reason for the change and whether it arises from CAPA, complaints, vigilance, supplier discontinuation, regulatory action or product improvement.

6.2 Supporting-evidence index

Each attachment shall have a unique identifier used consistently in the form and evidence matrix. For each document, state title, document number, version/date, relevant section and whether it is new, revised or unchanged. Provide a short explanation when an evidence type is not applicable.

6.3 Multiple related changes

As a general good practice, **one change application should relate to one product and one clearly defined change or set of technically interdependent changes**. This facilitates an efficient, transparent and traceable assessment.

However, a single form may cover multiple related changes only where their technical or regulatory relationship, combined impact and supporting evidence are clearly demonstrated unless duly justified and agreed with WHO.

Manufacturers should avoid combining **unrelated changes, changes affecting multiple products, or multiple changes with substantially different scopes or impact levels** within a single application. Such submissions may be considered insufficiently defined, may require separation into individual applications, or may result in delays to the assessment.

Where a change affects more than one prequalified product, the manufacturer shall clearly identify and justify the relationship between the affected products and demonstrate that the change, its impact and the supporting evidence are applicable to each product. **WHO may request separate submissions where product-specific assessment is necessary.**

Example:

New clinical evidence may demonstrate that device performance differs in a particular patient population, clinical condition or use setting from that previously established. This may require revision of the IFU, for example to modify the intended patient population, add a limitation or warning, revise performance claims, or provide additional information for interpretation of results. Such a change should be assessed based on the underlying new evidence and its impact on the prequalified product, and not solely as a labelling change.

Please also refer to Annex 5.

7. Submission, implementation and assessment

7.1 Before submission

- Complete internal change control and obtain appropriate internal acceptances.
- Confirm that the proposed category is supported by the risk and impact assessment.
- Confirm that all affected products, sites, documents and WHOPAR are identified.
- Complete PQDx_119 form and its evidence index; include redlined and clean proposed labelling/WHOPAR text where applicable.
- Ensure that files are searchable, legible, in English unless otherwise agreed, and named concisely.

7.1.1 Formatting requirements for submissions

The following requirements apply to the completed PQDx_119 form and all supporting documentation submitted as part of a reportable change request:

Requirement	Formatting requirement
Submission format	Submit the completed PQDx_119 form and all supporting documentation in accordance with the most up-to-date WHO instructions. Searchable, unprotected PDF files are preferred.
Organization	Present the submission in a clear and logical order. Identify each document and organize attachments according to the sections of the Change Request Form for WHO Prequalified In Vitro Diagnostic and Medical Devices.
Cover letter	A separate cover letter is not required.
File names	Use concise, descriptive file names that are meaningful to assessors. File names shall not exceed 50 characters and may contain spaces, standard hyphens, underscores and periods.
Characters not permitted in file names	Do not use: tilde (~); vertical bar (|); asterisk (*); forward slash (/); en dash or em dash; backward slash (\); apostrophes or quotation marks; greater-than or less-than signs (> or <); question mark (?); colon (:); number sign (#); or other non-standard symbols such as arrows, Greek letters, mathematical symbols or trademark symbols.
PDF creation	Generate PDF files directly from their source documents whenever feasible. Verify that content created using plug-ins or embedded applications displays correctly without access to those plug-ins or applications.
Scanned documents	Avoid scanned documents where possible, particularly for tables, graphs and figures. When scanning is necessary, ensure that the document is complete and legible and wear document control traceability. Apply optical character recognition (OCR) to scanned documents whenever feasible. Confirm that the text is searchable by selecting text and searching for a word or phrase contained in the document. OCR may be omitted for figures, images or other complex content when its use is not feasible.

Language	Submit all documents in English unless alternative arrangements have been agreed with WHO before submission.
Translations	Translations shall be prepared or certified by a qualified translator. Provide evidence confirming the accuracy of the translation and the translator's relevant credentials. Submit both the original-language document and its English translation.
Units of measurement	Express all measurements using the International System of Units (SI).
Completeness	A submission that does not meet these formatting requirements may be considered incomplete and may not be accepted for assessment.

7.2 Implementation control

A reportable change shall be submitted and accepted or approved by WHO before the changed product is released to the market. This requirement also applies to changes categorized as Low-impact unless WHO specifies otherwise. Validation or verification batches may be manufactured when necessary, under the QMS but shall not be commercially released before the applicable WHO decision. The manufacturer shall maintain segregation and traceability of pre-change and post-change product.

7.3 WHO assessment pathway

Change category /assessment pathway	WHO activity	Review / assessment rounds	Possible outcome(s)
Low impact — Review	WHO verifies the impact categorization, completeness and adequacy of the submitted information and conducts focused review/verification as needed.	**Up to 2 review rounds**, including up to **1 request for additional information/clarification**.	Change approved; additional information/clarification requested; reclassification to Moderate/High impact where justified; or change not approved/closed where applicable.
Moderate/High impact — Full assessment	WHO verifies the impact categorization and completeness, followed by a **full technical assessment** of the change and supporting evidence. Where required, additional assessment activities may include **manufacturing-site inspection and/or laboratory evaluation/testing**.	**Up to 3 assessment rounds**, including up to **2 requests for additional information**.	Change approved; additional information requested; additional assessment activities required; or change not approved/closed where applicable.
Moderate/High impact — Reliance/Abridged	The change **remains categorized as Moderate/High impact**. Where the **exact same change to the same**	Assessment is **abridged where reliance conditions are met**. Additional information may be	Change approved through the reliance/abridged

assessment, where eligible	**product/version** has already been assessed and approved by a **Recognized Regulatory Authority (RRA)**, WHO verifies reliance eligibility and assesses the RRA decision, supporting evidence and any WHO-specific information required.	requested where necessary. If reliance conditions are not met, the change proceeds through the applicable **full Moderate/High assessment pathway**.	pathway; additional information requested; or referral to full Moderate/High assessment where reliance conditions are not met.
New PQ application required	WHO confirms that the proposed change falls outside the identity and/or scope of the existing PQ/EUL listing.	**Not applicable — the change request process ends.**	Manufacturer proceeds with new prequalification application.

Changes relating primarily to the design, intended use, performance, labelling, software or other technical aspects of the product will be managed by the WHO Prequalification Assessment of Medical Devices Team. Changes relating primarily to the QMS, manufacturing site, manufacturing process, quality-control or release activities will be managed by WHO Prequalification Inspection Services.

Where a change affects both technical and QMS or manufacturing aspects, the assessment may be conducted jointly by the relevant WHO assessment and inspection teams. WHO will determine the appropriate allocation and coordination of the review.

7.3.1 Abridged assessment of Moderate/High-impact changes

A Moderate/High-impact change may be eligible for an abridged assessment when the manufacturer provides objective evidence that the same change to the same product has been assessed and approved by a Recognized Regulatory Authority (RRA), in accordance with WHO's abridged prequalification assessment procedures for medical devices and in vitro diagnostic medical devices.

The manufacturer shall demonstrate that the product, the proposed change, the affected version(s) or configuration(s), and the supporting evidence submitted to WHO are equivalent to those reviewed by the RRA. Any differences shall be identified and justified, including an assessment of their potential impact on quality, safety, or performance. Please refer to Annex 3.

When WHO confirms eligibility for the abridged pathway, the change shall be assessed in accordance with the applicable abridged assessment procedure. WHO may request additional information or determine that a full assessment is required where the reliance criteria are not met or where the available evidence is insufficient to support the proposed change.

Reliance on a recognized authority does not oblige WHO to reach the same regulatory conclusion and WHO may request any additional information deemed necessary.

7.4 WHO decision and change request review outcome

WHO will communicate the outcome of the assessment to the manufacturer in writing. Depending on the nature of the change and its potential impact on quality, safety, performance or QMS compliance, WHO may determine

that a manufacturing-site inspection, clinical evidence, performance evaluation or other assessment activity is required before the change can be accepted.

Where WHO approves the change, WHO will notify the manufacturer in writing. The manufacturer shall only commercially release the changed WHO prequalified/EUL device after receiving the applicable WHO approval and completing its controlled implementation activities.

Approval of a change does not remove the manufacturer's responsibility for implementation controls, post-market monitoring or compliance with other applicable regulatory obligations.

If the application or supporting data are incomplete, WHO shall provide the manufacturer with one opportunity to submit additional information for a Low-impact change and up to two opportunities for a Moderate/High-impact change. This results in a maximum of two review rounds for a Low-impact change and three review rounds for a Moderate/High-impact change, unless WHO specifies otherwise in writing.

If the supporting documentation does not meet WHO Prequalification requirements, or if the requested information is not provided within the specified timeframe, the change will be considered not ready for implementation. In such cases, WHO will reject the proposed change and close the application. The manufacturer shall submit a new change request once a complete and updated documentation package is available.

If any information or documentation submitted in support of a change application is found to be inaccurate, misleading, or falsified, WHO shall reject the proposed change and terminate the application. Where such findings raise concerns regarding the continued compliance, safety, performance, or eligibility of the product for WHO Prequalification or EUL listing, WHO shall take any additional actions deemed necessary, including a review of the product's listing status and, where appropriate, suspension or delisting of the product.

7.5 WHO public information updates

Where the proposed change requires an update to publicly available information, including product labelling, the manufacturer shall include in the reportable change application a redlined version of the relevant WHO Public Assessment Report (WHOPAR) with the updated sections as requested in PQDx_119 form. The redlined WHOPAR shall clearly identify all proposed additions, deletions and amendments. Updated affected public information shall be submitted in both redlined and clean versions, as applicable.

Following approval of the change, WHO shall update the WHOPAR, the WHOPIR and/or list of prequalified/EUL products, as applicable. Please see Annex 5.

8. Records, and failure to report

8.1 Records

The manufacturer shall retain the reportability decision, risk and impact assessment, approvals, supporting evidence, WHO correspondence, implementation date, affected lots or versions, and post-implementation monitoring records. Non-reportable changes remain subject to inspection, reassessment and other post-prequalification oversight where required by WHO.

8.2 Failure to report

Submitting reportable changes is mandatory for all WHO prequalified and EUL listed IVDs and MDs. The manufacturer is responsible for reporting each reportable change within the applicable timeframe and for keeping the product's prequalification information current.

Failure to report a reportable change may compromise:

Compliance with WHO requirements: an unreported or unapproved change shall result in the product no longer conforming to the applicable WHO requirements.

Procurement eligibility and continued listing: a product that no longer meets WHO prequalification requirements shall be subject to regulatory follow-up, suspension or delisting and may become ineligible for procurement by global health agencies.

As part of routine or risk-based post-prequalification monitoring, WHO Prequalification Inspection Services shall verify the manufacturer's compliance with its change-control and reporting obligations. This may include verification that reportable changes were submitted before implementation, that non-reportable classifications were adequately justified, and that accepted changes were implemented in accordance with the submitted documentation and the manufacturer's QMS.

Where a failure to report or appropriately control a change is identified during an inspection, it may be recorded as a nonconformity against the manufacturer's QMS. Independently of an inspection finding, failure to comply with the reporting obligations established in this guidance and the applicable Letter of Agreement shall result in the product no longer being considered compliant with its prequalified specifications and may lead to regulatory action, including publication of a Notice of Concern, suspension or delisting, as applicable.

8.3 Change request assessment fees

The manufacturer is responsible for the applicable fee contributing to the costs of reviewing the change documentation and updating or disseminating change information. The fee is non-refundable. Manufacturers shall refer to the current applicable WHO prequalification fee information available on the WHO Prequalification website.

Assessment of the change will commence after payment of the applicable fee. Payment does not guarantee approval of the proposed change. WHO will determine, on the basis of the assessment findings, whether the changed IVD or MD continues to meet the applicable prequalification requirements.

9. References & useful links

The following documents and webpages provide information to guide the manufacturer through WHO's prequalification assessment and are an integral part of this procedure.

References

[1] *GHTF/SG1/N071:2012 Definition of the Terms 'Medical Device' and 'In Vitro Diagnostic (IVD)* Medical Device'. Global Harmonization Task Force (GHTF) Steering Committee; 2012.

[2] *Good reliance practices in the regulation of medical products: high-level principles and considerations.* In: WHO Technical Report Series, No. 1033, Annex 10. Geneva: World Health Organization; 2021. Published 9 October 2021.

[3] *ISO 14971:2019. Medical devices – Application of risk management to medical devices*. Geneva: International Organization for Standardization. Geneva, Switzerland; 2019.

[4] *ISO 13485:2016. Medical devices – Quality management systems – Requirements for regulatory purposes.* Geneva, Switzerland: International Organization for Standardization; 2016.

Useful links

- ***PQDx_463 Q & A Change request for WHO prequalified and emergency use listed in vitro diagnostics. Geneva: World Health Organization.*** Available at: https://extranet.who.int/prequal/sites/default/files/document_files/PQDx%20463_Q_and_A%20Change%20Request%20for%20WHO%20PQ%20and%20EUL%20IVDs.pdf
- ***POSITION NOTE Medical device accessories supplied with WHO prequalified & EUL-listed IVDs.*** Geneva: World Health Organization. Available at: https://extranet.who.int/prequal/sites/default/files/document_files/Position_Note_on_Accessories_v1.pdf
- **Prequalification of In Vitro Diagnostics (IVDs)**. Geneva: World Health Organization. Available at: https://extranet.who.int/prequal/vitro-diagnostics.
- ***WHO's abridged prequalification assessment for in vitro diagnostics*.** Geneva: World Health Organization. Available at: https://iris.who.int/bitstreams/a18dbd6e-eef9-4bd9-9bc4-97da3e578e32/download
- **Post-prequalification Procedures and Fees: Prequalified IVDs.** Geneva: World Health Organization. Available at: https://extranet.who.int/prequal/vitro-diagnostics.
- **Prequalification of Medical Devices (MDs).** Geneva: World Health Organization. Available at: https://extranet.who.int/prequal/medical-devices/about-medical-device-prequalification
- ***WHO's abridged prequalification assessment for medical devices***. Geneva: World Health Organization; (PQDx_470). Available at: https://extranet.who.int/prequal/sites/default/files/document_files/PQDx_470%20Abridged%20prequalification%20assessment%20for%20medical%20devices.pdf
- **Post-Prequalification Procedures and Fees for Medical Devices.** Available at: https://extranet.who.int/prequal/medical-devices/post-prequalification-procedures-and-fees-medical-devices
- **Information for manufacturers on manufacturing site inspections**. Available at: https://extranet.who.int/prequal/inspection-services/vitro-diagnostics-and-male-circumcision-devices.
- ***Guidance for post-market surveillance and market surveillance of medical devices, including in vitro diagnostics.*** Geneva: World Health Organization; available at:https://iris.who.int/server/api/core/bitstreams/bf37980e-d286-4e4f-bda8-d49165619225/content

10. Contact

Any inquiries regarding reportable changes to WHO prequalified or EUL-listed IVDs and MDs should be addressed to: diagnostics@who.int.

Annex 1. Examples of reportable changes to IVDs

The tables below are non-exhaustive. “Low” and “H/M” are indicative starting points. The final category depends on the actual scope, risk assessment, evidence and relationship to other changes. “New PQ application” means that consultation with WHO is recommended before submission.

A1.1 IVDs

Examples apply to reagents, instruments, specimen collection components, calibrators, controls and associated software.

Example change	Likely pathway	Key rationale/expected evidence
Editorial correction to an IFU with no change in meaning, workflow, claims or warnings.	Low	Redline, clean copy and documented review confirming unchanged meaning and usability.
Addition of an IFU language using a controlled translation of unchanged approved content.	Low	Certified/controlled translation, equivalence review and updated artwork.
Change of product code or catalogue number only.	Low	Traceability mapping, declaration of no product change and proposed WHOPAR update.
Change to a non-critical packaging artwork element with no effect on identification, stability or use.	Low	Artwork comparison and impact assessment.
Like-for-like replacement of non-critical production equipment under the same validated process.	Low	Equivalence assessment, qualification and confirmation of unchanged specifications.
Change of critical reagent, antibody, antigen, primer/probe, enzyme, substrate or reference material.	H/M or new PQ application	Risk assessment, comparability, analytical performance, lot-to-lot and stability evidence; clinical evidence when bridging is insufficient.
Change to specimen type, matrix, collection device, sample volume or preparation method.	H/M or new PQ application	Analytical/clinical bridging, interference and usability evidence; intended-use assessment.
Change to cut-off, calibration, calculation, interpretation algorithm or result-reporting logic.	H/M	Software/analytical validation, clinical performance, risk, usability and labelling.
Extension of claimed shelf-life or in-use stability.	H/M	Protocol, completed real-time data or justified evidence, statistical analysis and updated labelling.
Shortening of shelf-life based on new stability information without a new safety signal.	Low; H/M if field action or safety impact	Root cause, risk assessment, affected-lot analysis, field action and revised labelling as applicable.
Transfer of reagent manufacture or final release testing to a new site.	H/M	Site/QMS evidence, technology transfer, process validation, comparability and release data.
Addition of a new indication, target condition, population or self-testing use.	New PQ application likely	Consult WHO; substantial performance, usability and labelling evidence expected.

Annex 2 Examples of reportable changes to MDs

The product-specific examples below are non-exhaustive. “Low” and “H/M” are indicative starting points. The final category depends on the actual scope, risk assessment, evidence and relationship to other changes. “New PQ application” means that consultation with WHO is recommended before submission.

A2.1 Condoms

Examples apply to male and female condoms, including materials, lubricant, packaging and associated manufacturing controls.

Example change	Likely pathway	Key rationale/expected evidence
Change to product name, catalogue number or manufacturer contact details only.	Low	Traceability mapping, declaration of no technical change and updated public information.
Minor artwork or translation update with no change in warnings, instructions or symbols.	Low	Redline, clean copy and controlled translation review.
Addition of a pack size using the same primary package and validated sealing configuration.	Low or H/M	Packaging rationale; transport and stability evidence if configuration or protection changes.
Change in condom colour using an already qualified colorant at an equivalent concentration.	H/M	Toxicological/biocompatibility assessment, material compatibility, performance and stability evidence.
Change in latex formulation, synthetic material, thickness, dimensions or surface texture.	H/M or new PQ application	Design verification, physical performance, biocompatibility, stability and clinical/usability justification as applicable.
Change in lubricant identity, formulation, quantity or supplier.	H/M	Chemical characterization, biocompatibility, compatibility, performance and stability.
Change in primary foil, sealant or sealing parameters.	H/M	Package integrity, seal validation, ageing/stability and transport evidence.
Transfer of dipping, vulcanization, electronic testing, lubrication or packaging to a new site.	H/M	Transfer plan, process validation, site/QMS evidence and comparative lot data.
Relaxation of freedom-from-holes, bursting, dimensions or other release acceptance criteria.	H/M	Risk justification and validation; acceptance is not presumed.
Addition of a new intended use or materially different user population.	New PQ application likely	Consult WHO; clinical, performance, usability and labelling evidence expected.

A2.2 Intrauterine devices (IUDs)

Example change	Likely pathway	Key rationale/expected evidence
Product-code update or administrative manufacturer detail with no product/QMS change.	Low	Traceability and proposed public-information update.
Editorial IFU correction with no change in insertion/removal instructions or warnings.	Low	Redline, clean copy and usability/meaning review.
Deletion of a non-essential accessory with demonstrated no effect on safe insertion/removal.	Low or H/M	Risk and usability assessment; justification of accessory status.
Change to IUD frame polymer, radiopaque additive, copper wire/sleeve or active surface area.	H/M or new PQ application	Material characterization, biocompatibility, mechanical/chemical performance, stability and clinical bridging.
Change to dimensions, geometry, retrieval threads or inserter design.	H/M	Bench performance, insertion/removal forces, deployment accuracy, usability, biocompatibility and risk evidence.
Change to sterilization method, cycle or sterilization site.	H/M	Sterilization validation, bioburden, material compatibility, packaging and shelf-life evidence.
Change to primary sterile barrier material, configuration or sealing process.	H/M	Package validation, integrity, transport and ageing evidence.
Extension of shelf-life.	H/M	Real-time ageing or justified supporting evidence, package integrity and functional testing.
Transfer of molding, copper assembly, inserter assembly or final release to a new site.	H/M	Site/QMS evidence, process validation, transfer and comparative lot data.
New duration-of-use claim, new population or new therapeutic/contraceptive claim.	New PQ application likely	Consult WHO; substantial clinical and benefit-risk evidence expected.

Examples apply to copper-bearing and other prequalified IUD configurations, inserters and sterile barrier systems.

A2.3 CAD software for tuberculosis

Examples apply to stand-alone or integrated software that analyzes chest radiographs to support TB screening or triage. Software-only changes must still be assessed for clinical, usability and cybersecurity impact.

Example change	Likely pathway	Key rationale/expected evidence
Correction of typographical text in help content with no workflow or meaning change.	Low	Redline and documented review.
Cybersecurity patch to a third-party library with no change in intended functionality or performance.	Low or H/M	Vulnerability assessment, regression testing, software bill of materials and confirmation of no performance impact.
Operating-system or hardware compatibility update without algorithm change.	Low or H/M	Compatibility, installation, regression, performance and cybersecurity testing.
User-interface layout change that does not alter result presentation, interpretation or workflow.	Low	Usability impact assessment and regression evidence.
Change in result display, alerts, threshold controls or user workflow.	H/M	Usability validation, risk assessment, software verification/validation and labelling.
Change to model weights, training data, image preprocessing, score calibration or decision threshold.	H/M	Locked-version identification, dataset provenance, analytical/clinical performance, subgroup analysis, regression and risk evidence.
Addition of a new imaging device, detector, image format or deployment environment.	H/M	Compatibility and performance bridging across representative systems and sites.
Change to cloud hosting, data flow, encryption, authentication or access-control architecture.	H/M	Cybersecurity threat model, privacy/data integrity assessment, availability, validation and rollback plan.
Change from locked to continuously learning or adaptive behaviour.	New PQ application likely	Consult WHO; predetermined change-control plan and substantial validation/governance evidence expected.
New claim for diagnosis, autonomous decision-making, a new population or a new disease.	New PQ application likely	Consult WHO; new intended use and clinical performance evidence expected.

A2.4 Male circumcision devices

Examples apply to WHO prequalified male circumcision devices and their supplied sizing, application, removal and post-procedure accessories, as applicable.

Example change	Likely pathway	Key rationale/expected evidence
Change to the product name, product code or manufacturer contact details only, with no technical or QMS change.	Low	Traceability mapping, declaration of no technical change and proposed update to public information.
Editorial or translation update to the instructions for use with no change in meaning, warnings, training requirements or procedural steps.	Low	Redlined and clean copies, controlled translation and documented review confirming unchanged meaning and usability.
Removal or replacement of a non-critical accessory, such as a bandage or measuring aid, with demonstrated equivalent function and no effect on safe use.	Low or H/M	Accessory equivalence, risk assessment and usability justification.
Change to the intended population, including an expansion of the approved age range.	H/M or new application	Clinical and usability evidence, updated benefit-risk assessment, training implications and revised labelling; consult WHO on application pathway.
Addition, deletion or relaxation of a contraindication, warning, precaution or limitation.	H/M	Clinical/safety rationale, post-market data, risk-management update and revised labelling.
Change to the approved circumcision procedure, application or removal method, placement duration, follow-up schedule or user training requirements.	H/M	Usability and training validation, clinical or performance evidence, risk assessment and updated instructions for use.
Change to the device operating principle, deployment mechanism or removal mechanism.	H/M or new application	Design verification and validation, clinical evidence, usability, risk and application-pathway assessment.
Change to device dimensions, geometry, configuration or sizing method that may affect fit, tissue interaction, placement or removal.	H/M	Bench and mechanical testing, sizing validation, usability, clinical bridging and risk assessment.
Change to patient-contacting materials, material formulation,	H/M	Chemical characterization, biocompatibility, material compatibility, functional performance and stability.

surface coating, lubricant, additive or colorant.		
Change to mechanical or performance specifications, including retention, compression, breakage, leakage or removal-force requirements, as applicable to the device design.	H/M	Bench verification, acceptance-criteria justification, clinical relevance and updated risk analysis.
Extension of shelf-life or change to storage or transport conditions.	H/M	Real-time ageing or justified supporting evidence, packaging integrity, transport validation and functional performance.
Change to the sterilization method, cycle, load configuration, release method or sterilization site.	H/M	Sterilization validation, bioburden, material compatibility, sterile-barrier and shelf-life evidence.
Change to the primary sterile-barrier material, packaging configuration, sealing process or seal acceptance criteria.	H/M	Packaging and seal validation, integrity, transport and ageing evidence.
Transfer of molding, assembly, packaging, sterilization, testing or final release to a new site, or change of a critical supplier.	H/M	Site and QMS evidence, supplier controls, technology-transfer documentation, process validation and comparative lot data.
Change arising from complaints, vigilance, field safety corrective action or CAPA that may affect safety or performance.	H/M	Root-cause investigation, affected-product assessment, CAPA effectiveness, risk update and field-action documentation, as applicable.

Annex 3. Supporting evidence matrix for abridged assessment

Reliance/recognized-authority evidence			
Document/evidence	**Low impact**	**H/M impact**	**Notes**
Completed PQDx_119 form	Required	Required	Signed, complete and internally consistent. Complete all applicable sections and justify items identified as not applicable.
Current-vs-proposed comparison	Required	Required	Clearly identify each distinct modification and include all affected products, codes, models/configurations, versions, sites, suppliers and controlled documents, as applicable.
Reportability & category rationale	Required	Required	Link conclusions to the impact and risk assessment. Include the applicable criteria, cumulative impact and justification that the change does or does not reach the threshold for a new PQ application.
Risk-management evidence	Summary, relevant extract or change-specific assessment	Detailed change-specific assessment and relevant Risk Management File update	Include any new or modified hazards, hazardous situations, foreseeable sequences of events, risk control measures, residual risks and benefit-risk conclusions resulting from the proposed change.
Implementation, transition and change management plan	Required, proportionate to the change	Required	Describe how the change will be managed and implemented, taking into account the outcome of the impact and risk assessment. Include any required studies, verification and validation activities, responsibilities, implementation milestones, timelines and approval gates, as well as transition arrangements between the previous and modified product/configuration. Address inventory and distribution arrangements where applicable, customer communication, training and controls preventing unauthorized market release.

Verification/validation evidence	As applicable	Required when affected	Provide evidence proportionate to the nature and impact of the change, including applicable protocols, acceptance criteria, results, deviations and conclusions. Demonstrate continued conformity of the changed product.
Design-change evidence	As applicable	Required when design is affected	Include affected design inputs/outputs, design review, verification/validation and traceability, as applicable. Applies to IVDs and MDs, including devices incorporating software.
Analytical performance evidence – IVD	As applicable	Required when affected	For IVDs, address relevant analytical performance characteristics, such as precision, analytical sensitivity/specificity, measuring range, interference, specimen-related effects and reagent/instrument compatibility, as applicable.
Clinical performance evidence – IVD	As applicable	Required when affected	For IVDs, provide clinical performance evidence proportionate to the change where clinical sensitivity/specificity, target population, result interpretation, cut-offs, reference intervals or performance claims may be affected.
Clinical evidence/ clinical evaluation –MDs	As applicable	Required when affected	For MDs, provide relevant clinical evidence or an updated clinical evaluation where the change may affect clinical safety, performance, intended purpose, claims or benefit risk.
Materials/components and product safety evidence –MDs	As applicable	Required when affected	Address affected materials, components, accessories and patient-contacting characteristics and, where applicable, biological, electrical, mechanical, radiation or other relevant safety/performance evidence.
Manufacturing/process validation	As applicable	Required when process, site or critical manufacturing controls are affected	Include manufacturing transfer, facility/equipment qualification, process validation, release controls and comparative evidence, as applicable to the device and change.

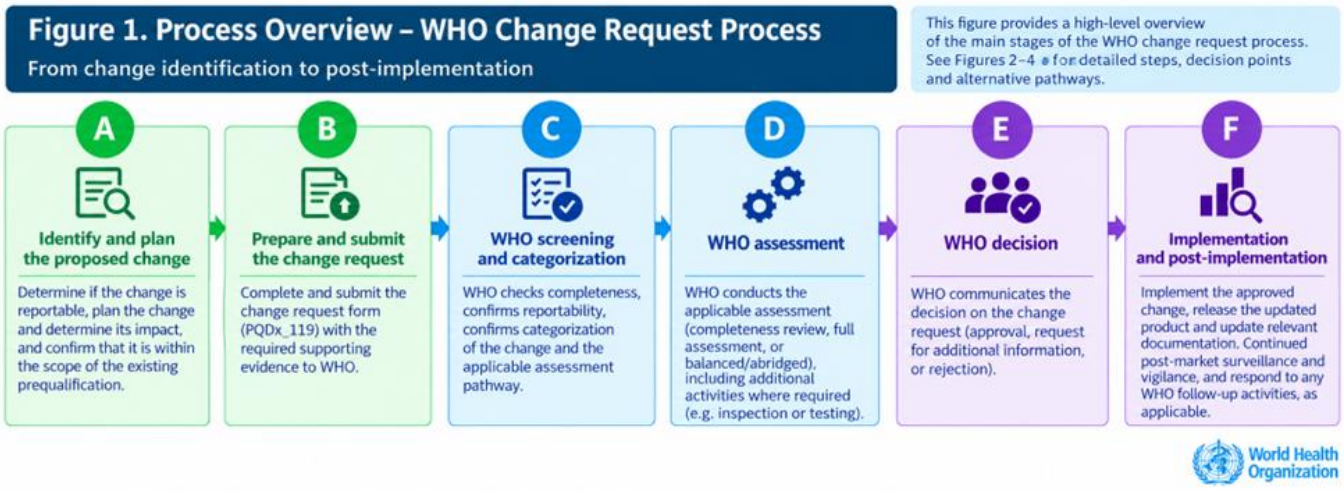
Supplier/outsourced-process evidence	When affected	Required when a critical supplier, material, component, service or outsourced process is affected	Include criticality assessment, supplier qualification and monitoring, quality agreements, incoming controls, comparability evidence and supply-continuity arrangements, as applicable.
Software lifecycle/configuration-management evidence	As applicable	Required when affected	For devices incorporating software, include relevant requirements, architecture/design, configuration and version control, traceability, verification/validation, regression testing, anomaly resolution and software release evidence.
AI/ML or algorithm evidence	As applicable	Required when affected	For devices incorporating AI/ML or other algorithmic functionality, address changes to the model/algorithm, input or training/validation data, preprocessing, decision logic or thresholds, outputs and performance characteristics, as applicable.
Cybersecurity evidence	As applicable	Required when affected	For devices with cybersecurity-relevant functionality, include applicable threat modelling, vulnerability assessment, security architecture, access controls, data integrity, software dependencies/SBOM, update mechanisms and cybersecurity verification/validation.
Usability/human factors evidence	As applicable	Required when affected	Address changes affecting user interaction, workflow, user interface, result/output interpretation, use environment, foreseeable misuse, training or use-related risks.
Interoperability/interface evidence	As applicable	Required when affected	Address interfaces with other devices, accessories, software, networks or systems, including compatibility, input/output integrity, data or signal exchange and backward compatibility, as applicable.
Stability/shelf-life/transport evidence	As applicable	Required when affected	Include applicable protocols, completed or interim data, acceptance criteria and scientific justification for pending data. For IVDs, consider reagent, calibrator, control and opened/on-board stability where relevant.

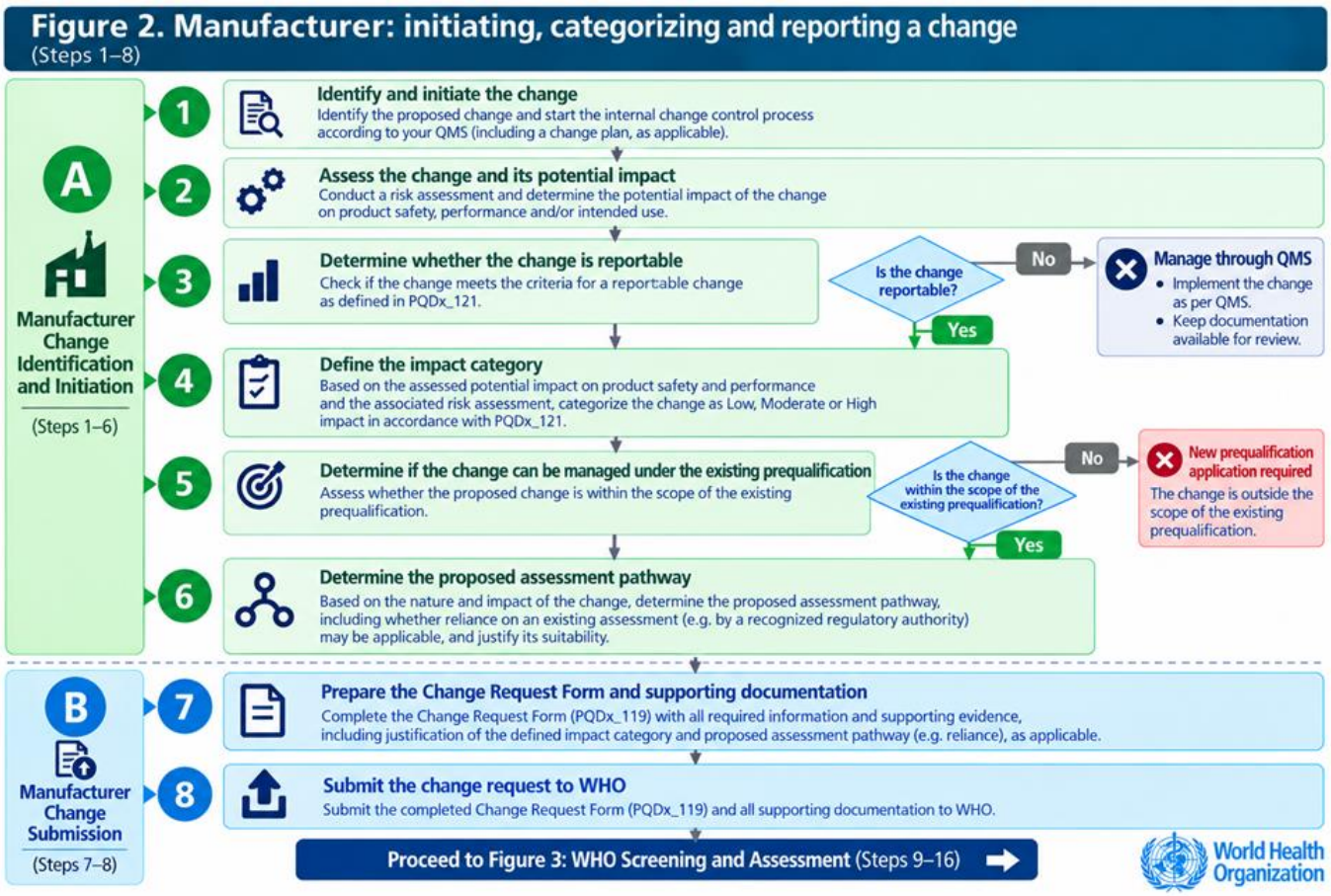
Packaging/sterilization/reprocessing evidence	As applicable	Required when affected	For devices, address packaging integrity, sterile-barrier systems, sterilization, cleaning, disinfection or reprocessing validation and associated changes to shelf-life or product integrity.
Labelling/IFU/WHOPAR redline & clean copy	When affected	When affected	Ensure intended use/purpose, indications, claims, contraindications, warnings, limitations, performance information, identifiers and other affected information are consistent with the proposed change and supporting evidence.
QMS/site evidence	When affected	Required when critical	Include affected QMS processes, certificates and scope, manufacturing/testing sites, audit or inspection information, responsibilities and applicable procedural controls.
Post-implementation/PMS and vigilance evidence	Required, proportionate to the change	Required	Define post-implementation verification, acceptance criteria, monitoring, complaints/trends, vigilance, corrective-action readiness and any additional post-market activities arising from the change.
Reliance/recognized-authority evidence for abridged assessment	**Required when an abridged assessment is sought**	**Required when an abridged assessment is sought**	Demonstrate that the **exact same change** to the same product/version has been assessed and approved by a WHO-recognized authority under the applicable reliance/abridged-assessment framework. Provide the authority and jurisdiction, product/version covered, change assessed, decision and date, relevant assessment evidence, and any differences or exclusions.

Annex 4. Manufacturer decision checklist

No.	The applicant shall check and answer the following questionnaire:	Yes/No/NA
1	Is the current and proposed state of the device/product described precisely?	
2	Are all affected product codes, versions, sites, suppliers and markets identified?	
3	Have related and cumulative changes been considered together?	
4	Are all affected dossier, WHOPAR, WHOPIR and labelling sections identified?	
5	Does the change remain within the identity and scope of the prequalified device?	
6	Have effects on quality, safety, performance, usability, cybersecurity and intended use been assessed?	
7	Have stability, sterility, packaging, transport and environmental effects been assessed where relevant?	
8	Are new or changed hazards, risk controls and residual risks documented?	
9	Is the proposed pathway supported by evidence burden and uncertainty?	
10	Does PQDx_119 form cross-reference every attachment clearly?	
11	Are both redlined and clean proposed texts supplied where information changes?	
12	Is commercial release prevented until WHO approval?	

Annex 5. WHO reportable change process for prequalified and EUL listed IVDs and MDs.





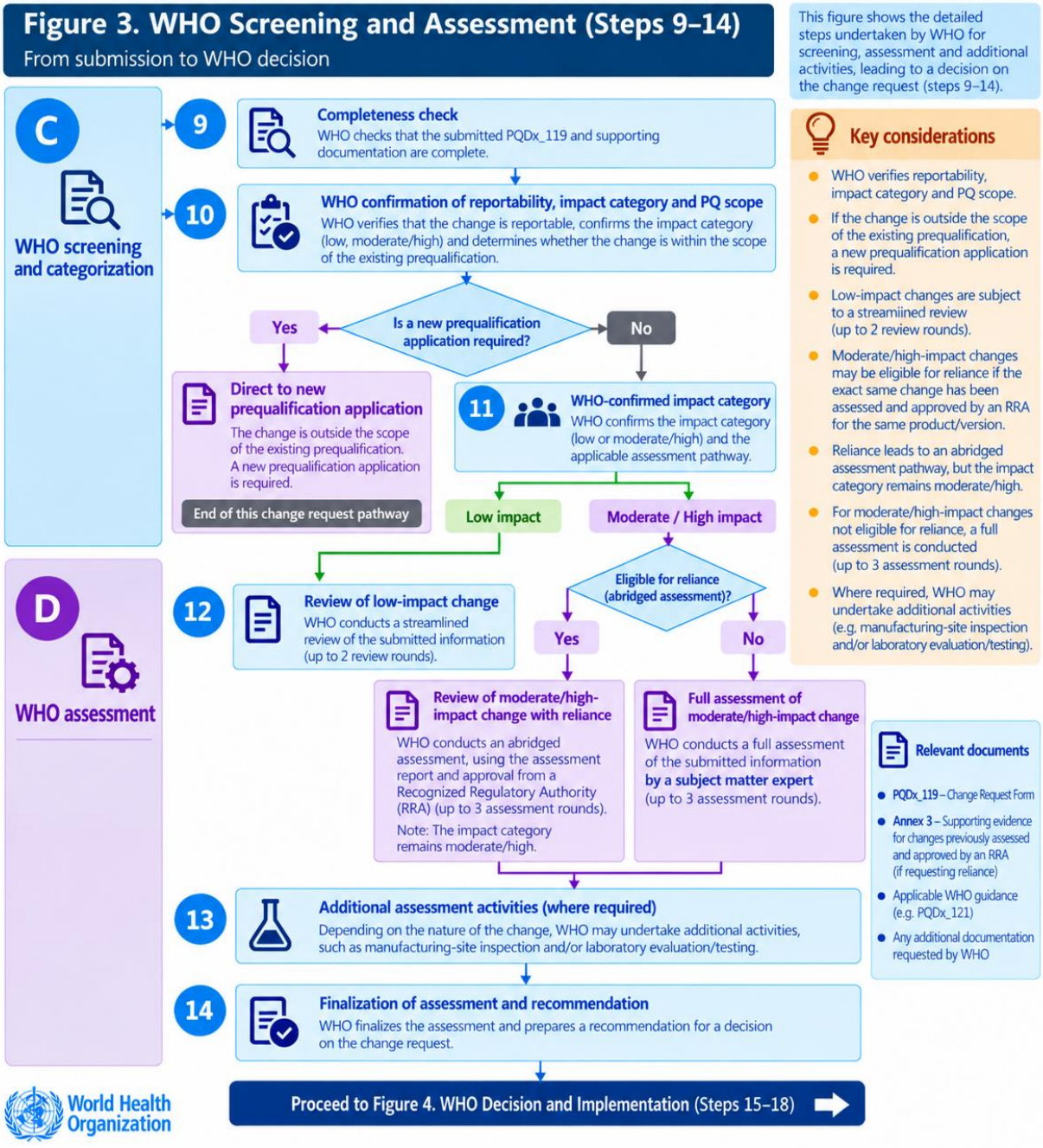
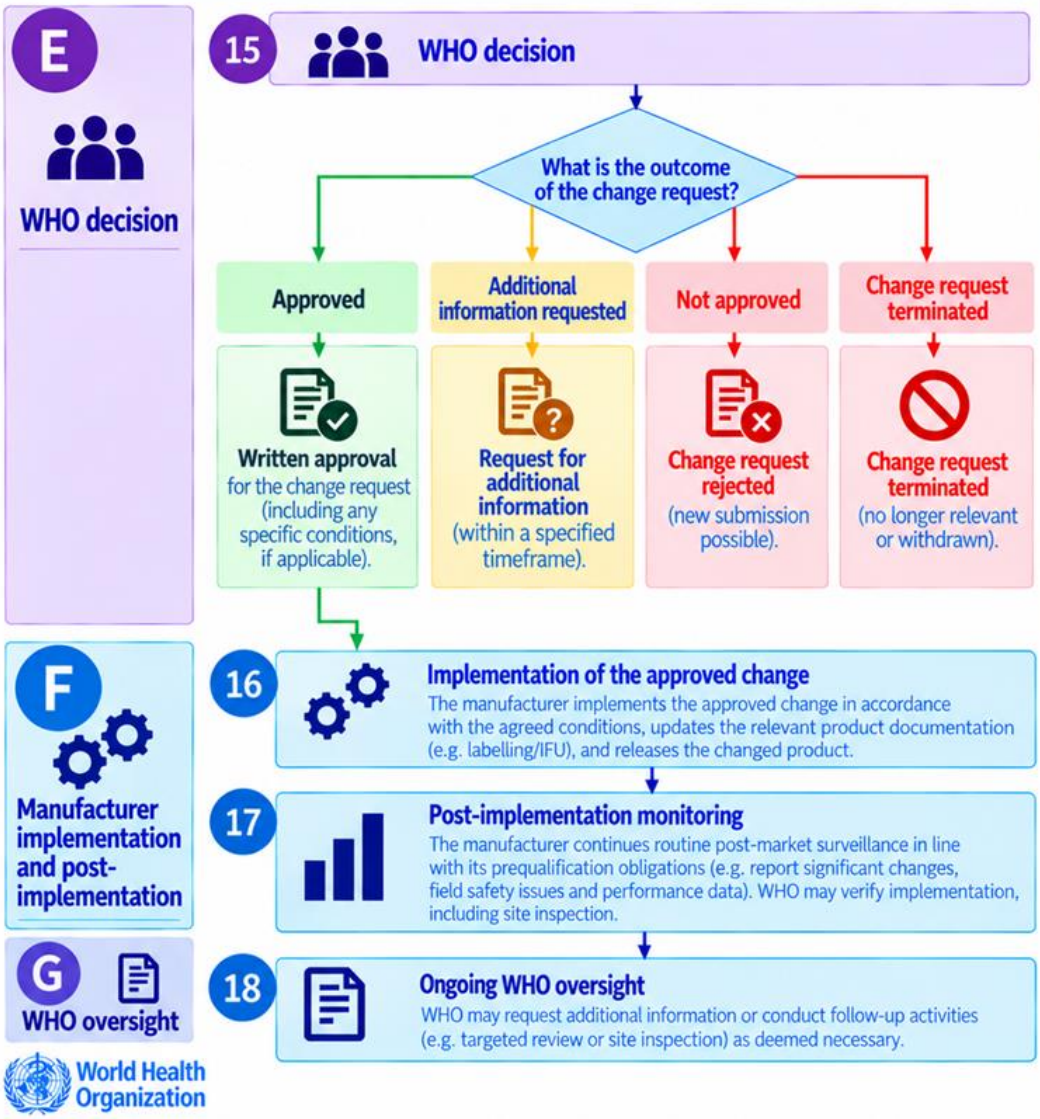


Figure 3. WHO Screening and Assessment (Steps 9–14)
From submission to WHO decision
This figure shows the detailed steps undertaken by WHO for screening, assessment and additional activities, leading to a decision on the change request (steps 9–14).
C
WHO screening and categorization
9
Completeness check
WHO checks that the submitted PQDx_119 and supporting documentation are complete.
10
WHO confirmation of reportability, impact category and PQ scope
WHO verifies that the change is reportable, confirms the impact category (low, moderate/high) and determines whether the change is within the scope of the existing prequalification.
Is a new prequalification application required?
Yes
No
Direct to new prequalification application
The change is outside the scope of the existing prequalification. A new prequalification application is required.
End of this change request pathway
11
WHO-confirmed impact category
WHO confirms the impact category (low or moderate/high) and the applicable assessment pathway.
Low impact
Moderate / High impact
D
WHO assessment
12
Review of low-impact change
WHO conducts a streamlined review of the submitted information (up to 2 review rounds).
Eligible for reliance (abridged assessment)?
Yes
No
Review of moderate/high-impact change with reliance
WHO conducts an abridged assessment, using the assessment report and approval from a Recognized Regulatory Authority (RRA) (up to 3 assessment rounds).
Note: The impact category remains moderate/high.
Full assessment of moderate/high-impact change
WHO conducts a full assessment of the submitted information by a subject matter expert (up to 3 assessment rounds).
13
Additional assessment activities (where required)
Depending on the nature of the change, WHO may undertake additional activities, such as manufacturing-site inspection and/or laboratory evaluation/testing.
14
Finalization of assessment and recommendation
WHO finalizes the assessment and prepares a recommendation for a decision on the change request.
Proceed to Figure 4. WHO Decision and Implementation (Steps 15–18)
World Health Organization
Key considerations
WHO verifies reportability, impact category and PQ scope.
If the change is outside the scope of the existing prequalification, a new prequalification application is required.
Low-impact changes are subject to a streamlined review (up to 2 review rounds).
Moderate/high-impact changes may be eligible for reliance if the exact same change has been assessed and approved by an RRA for the same product/version.
Reliance leads to an abridged assessment pathway, but the impact category remains moderate/high.
For moderate/high-impact changes not eligible for reliance, a full assessment is conducted (up to 3 assessment rounds).
Where required, WHO may undertake additional activities (e.g. manufacturing-site inspection and/or laboratory evaluation/testing).
Relevant documents
PQDx_119 – Change Request Form
Annex 3 – Supporting evidence for changes previously assessed and approved by an RRA (if requesting reliance)
Applicable WHO guidance (e.g. PQDx_121)
Any additional documentation requested by WHO

Figure 4. WHO Decision and Implementation (Steps 15–18)

From assessment completion to implementation and post-implementation activities



This figure shows the final steps in the change request process, from the WHO decision to the implementation of the approved change and post-implementation monitoring (steps 15–18).

Key considerations

- WHO communicates the decision in writing.
- Implementation can only proceed after written approval.
- Requests for additional information return to the relevant assessment step (see Figure 3).
- Rejected or terminated changes are not implemented. under the existing prequalification.

Relevant documents

- Written WHO decision letter
- Updated product documentation (e.g. labelling, IFU)
- Post-market surveillance summary
- Any additional documentation requested by WHO