World Health Organization

Table of Contents [ToC]

Product dossier checklist

Prequalification of in vitro diagnostics

The attached Product Dossier contains information in support of the previously submitted Prequalification of in vitro diagnostics - Pre-submission form (Document PQDx_015) for the following product:

Application Number:	
Product Name:	
Manufacturer Name:	

Table of Contents [ToC] Product dossier checklist – Prequalification of In Vitro Diagnostics

WHO/MHP/RPQ/PQT/2022.03

Instructions for the reader:

The information in this checklist is used in the screening for completeness and dossier review phase of the prequalification assessment. WHO requires that a product dossier is submitted in the "Table of Contents" (ToC) format, described in the IMDRF document IMDRF/RPS WG/N13 FINAL:2019 (Edition 3). In this document sections are numbered according to IMDRF ToC format. As the IMDRF ToC is comprehensive in nature, not all headings are required for WHO prequalification and are excluded.

- All sections listed in the table are required to be submitted as part of the product dossier for full assessment unless indicated "if applicable". Some additional information may be required – please refer to the Technical Specifications Series (TSS) document that corresponds to the product that is the subject of the application. Please add document references, as described below, accordingly.
- The requirements for an abridged dossier submission are noted in the column "Abridged requirements" (R= required, NR= not required).
- Insert **Yes or No** in the "Provided" column whether each section is supplied. Where information is not available or the field is not applicable, type in **N/A**.
- In the "Location" column, state the associated page numbers and volume or section number as required for each field.
- The manufacturer is requested to submit this form as a searchable PDF file. The Manufacturer Declaration on page 16 of this document may be signed electronically.

Dossier Content Requirement	Provided	Location	Abridged requirements
DOSSIER FORMAT			
Product Dossier Submission Format			
One electronic copy of the product dossier submitted			R
Layout and Order			
Proper formatting of page numbers for example page *1 of 2*, *2 of 2*, etc., used			R
The submission is clearly divided into sections as described and all pages are numbered			R
Font sizes are easily legible			R
Electronic Copy Requirements			
The electronic copy is in PDF form with no password required			R
The name of the file is descriptive and doesn't contain any of the noted special characters			R
Language and Units of Measurement			

Dossier Content Requirement	Provided	Location	Abridged requirements
English language and International System of Units of measure used			R
Any translations have been carried out by a certified translator (if applicable)			R
1. ADMINISTRATIVE			
1.1 Cover letter			
The Letter of Agreement is attached to the front page of the dossier			R
The information concerning the product in the dossier provided is the same in the Letter of Agreement and the Prequalification Dossier			R
1.2 Submission table of contents			
This table of contents appears at the beginning of the product dossier			R
Each section is numbered and named according to the Product Dossier Checklist			R
The physical pages of the dossier and the page numbers in this checklist correspond; all applicable TSS-related sections are clearly indicated			R
1.3 List of terms/Acronyms			
Abbreviations and acronyms used in the submission are defined			R
1.4 Application form/Administrative information			
A copy of the completed PQDx_015 *Pre-Submission Form* to which this submission relates is included			R
The information in the product dossier is consistent with the completed PQDx_015 *Pre-submission Form*: if not, any differences are explained and supporting evidence provided			R
1.5 Listing of devices			
A list of configurations is included, if applicable			R

Dossier Content Requirement	Provided	Location	Abridged requirements
A list of accessories and/or other products to be used with the IVD is included, if applicable			R
1.6 QMS or other regulatory certificates			
A certified copy of the manufacturer's quality management system certificate is included			R
1.7 Free sale certificate / Certificate of marketing authorisation			
If applicable, a list of National Regulatory Authorities that have provided current regulatory approval for the supply of the IVD and the type of regulatory approval obtained is included			R
Certificates provided by National Regulatory Authorities where the IVD is approved for use are included, if applicable			R
Information relating to export-only regulatory approvals are clearly identified			R
1.8 User fees			
Attestation of payment is the second page of the dossier			R
1.12 Statements/Certifications/Declarations of conformity			
1.12.5 Truthful and accurate statement			R
The Manufacturer Declaration at the end of this checklist, that all the information provided in the product dossier is current and correct, has been signed and dated			R
2. SUBMISSION CONTEXT			
2.4 Device description			
2.4.1 Comprehensive device description and principle of operation			
A description of the principle of the assay method/instrument principles of operation are provided			R

Dossier Content Requirement	Provided	Location	Abridged requirements
A description of the components and reactive ingredients are included			R
Photographs of all kit components, both packaged and individual, are included			R
A description and photographs of the specimen collection and transport materials are provided			R
A statement as to whether the test output is qualitative, semi-quantitative or quantitative			R
A statement as to whether the product is automated, semi-automated or manually operated			R
For automated and semi-automated assays: a description of the dedicated instrumentation, or for assays that do not require dedicated instrumentation; a description of the appropriate instrumentation characteristics; and a description of the dedicated consumables.			R
If applicable, there is a description of software to be used with the product			R
2.4.1 (g) Biological material			
A table of all biological materials is provided that includes: identity of each material, origin, source (e.g. blood, tissue etc) and where it is used in the product a			NR
For each biological material, a description of the steps taken to reduce transition or infection risk is provided			
If applicable, a determination of the residual risk of transmission/infection to the user is provided and how the user is informed of any residual risk.			NR
2.4.2 Material specifications			
A list of all critical raw materials and components used in the product is provided			NR
For each identified raw material or component, details of the formulation and composition are provided			NR

Dossier Content Requirement	Provided	Location	Abridged requirements
Sources of IVD component materials are identified			NR
2.4.4 History of development			NR
A table summarizing all versions of the product referred to in the dossier is provided, if applicable			NR
Date of design lockdown (design freeze) is provided			NR
Any changes to the product have been documented and supporting evidence provided			NR
2.5 Indications for use and/or intended use			R
2.5.1 Intended use; Intended purpose; Intended user; Indications for use			R
The intended use of the IVD, testing population, user, specimen types, analyte, and clinical indication are included			R
2.5.2 Intended environment / setting for use			R
The setting(s) where the device is intended to be used is included			R
2.6 Global market history			
2.6.1 Global market history			R
There is a list of all countries in which the product under assessment is currently supplied and the year when supply started			R
All regulatory versions of the product are identified and the version being submitted for assessment is indicated			R
The regulatory version to which the information in the product dossier relates is identified			R
2.6.2 Global incident reports and recalls			
If applicable, a list of all adverse events within the last five years with details of the corrective and preventive action taken is provided			NR

Dossier Content Requirement	Provided	Location	Abridged requirements
If applicable, details are provided regarding any situations in which this product was rejected by a National Regulatory Authority or regulatory approval was withdrawn			NR
2.6.4 Evaluation / inspection reports			
The most recent full and subsequent surveillance regulatory inspection reports issued by the certification body are included			R
2.7 Other submission context information			
2.7.1 Global prices			
The minimum and maximum global price of supply for the product for the last financial year are included			R
2.7.2 Training and support networks			
For each country, detailed information about the training and support network is provided, including whether manufacturer representatives are located in the country			NR
3. NON-CLINICAL EVIDENCE			
3.2 Risk management			
There is a summary report of the risks identified during the risk analysis process			R
A description of how risks have been controlled to an acceptable level			R
A signed conclusion with evidence that the remaining risks are acceptable is presented			R
There is evidence that the risk analysis is part of the manufacturer's risk management plan			R
When applicable, specific standards/guidelines recommended by the WHO are identified			R
3.3 Essential principles checklist			
A checklist in the form of a table that lists all relevant material is included			NR

Dossier Content Requirement	Provided	Location	Abridged requirements
This checklist is filled in as per the description and examples provided in the instructions and annexes			NR
3.5 Analytical performance			
Product performance specifications and associated validation and verification studies with the following information provided for each section: a study description, study summary, full study protocol and report			
3.5.1 Stability of specimen(s)			
Studies and required information to support stability, storage and where applicable transport condition claims for each specimen type are included			NR
3.5.2 Validation of specimens			
The different specimen types that can be used with the product are identified			NR
Studies to support each specimen type are included			NR
3.5.3 Metrological traceability of calibrator and control material values			
Detailed information about the traceability of values assigned to calibrators and control materials supplied with the assay (if applicable) and those used in the manufacturing process.			NR
3.5.4 Accuracy of measurement			
3.5.4.1 Trueness			NR
Studies to establish trueness of measurement are provided, where applicable			NR
3.5.4.2 Precision of measurement (repeatability and reproducibility)			

Dossier Content Requirement	Provided	Location	Abridged requirements
Studies and information needed to establish within-run variability are included			R
Studies and information to establish the appropriate types of variability (between-run, -lot, -operator, -site, -instrument, etc) are included			R
The use of specimens that represent the full range of expected analyte concentration are included			R
If applicable, studies to establish precision undertaken by non-laboratory personnel are provided			R
3.5.5 Analytical sensitivity			
Studies required to establish analytical sensitivity are included			NR
3.5.6 Analytical specificity			
Studies to evaluate the effects of potentially interfering and cross-reacting substances/agents on the assay are included			NR
3.5.7 High dose hook effect			
Studies to establish the absence of high dose hook effect are provided, if applicable			NR
3.5.8 Measuring range of the assay			
Studies that define the measuring range of the assay, and a description of how this was established are included, if applicable			NR
3.5.9 Validation of assay cut-off			
Studies on how the assay cut-off is determined are included, if applicable			NR
3.5.10 Validation of assay procedure			
For products where a reading interval is specified, a validation study of the critical time points is included			NR
3.6 Other studies			
3.6.4 Usability / Human factors			

Dossier Content Requirement	Provided	Location	Abridged requirements
The test environment and its relation to the intended environment are stated			R
There is a discussion of what tests were considered for the device and why they were/were not performed			R
There is a discussion to support why the evidence presented is sufficient to support the application			R
If performance studies that have been conducted in other sections of the product dossier include human factors/usability end points, reference to the studies and endpoints are made			R
Label comprehension study is provided, if applicable			R
Interpretation of results study is provided, if applicable			R
3.6.5 Stability of the IVD			
3.6.5.1 Claimed shelf life			
Studies supporting claimed shelf life are provided			R
Testing intervals and acceptance criteria are described			R
If applicable, the method used for accelerated studies is identified			R
The results and conclusions clearly demonstrate that the product will be effective at the end of its claimed shelf-life after being subjected to a simulated transport challenge			R
3.6.5.2 In-use stability			
Studies are provided for the in-use stability of each labile component			R
Testing intervals and acceptance criteria are described			
The studies reflect routine use of the device (open vial stability and/or on-board stability for automated instruments, and/or multiple access of reagent bottles)			R
If applicable, supporting data for calibration stability claims is provided			R
Conclusions clearly identify the claimed in-use stability			R

Dossier Content Requirement	Provided	Location	Abridged requirements
3.6.5.3 Shipping stability			
Studies are provided for drop-shock testing of the product			R
A separate shipping stability study is not necessarily required in this section (real-time shelf-life determination shall be preceded by a simulated transport challenge; see section 3.6.5.1)			R
3.8 Other evidence			
3.8.1 Testing in performance panels and other TSS-specific evidence			
Studies are provided to fulfil the product's corresponding technical specification (TSS) requirements, if applicable			NR
4. CLINICAL EVIDENCE			
4.2 Overall clinical evidence summary			
4.2.1 Expected values / reference ranges			
The values to expect in healthy normal patients versus affected patients is provided, if applicable			NR
4.2.3 IVD medical device specific clinical studies			
All claims for clinical performance are supported by well-designed performance evaluations. These may include evaluations carried out or coordinated by the manufacturer, as well as evaluations carried out by bodies wholly independent of the manufacturer.			NR
Testimonials are not included as evidence of performance			NR
4.5 Other clinical evidence			
4.5.1 Qualification of usability			
A clinical evaluation of the usability of the product is provided to fulfil the product's corresponding technical specification (TSS) requirements, if applicable (i.e. observed untrained self-testing users).			NR
5 LABELLING AND PROMOTIONAL MATERIAL			

Dossier Content Requirement	Provided	Location	Abridged requirements
5.2 Product/package labels			
The product dossier contains a complete set of labels associated with the product			R
5.3 Package insert/Instructions for use			
A copy of the current instructions for use are included and these instructions include all relevant information			R
5.6 Technical / operators manual			
If applicable, there is a copy of the instrument manual/associated operator manuals included			R
5.8 Other labelling and promotional materials			
If applicable, copies of any other instructional materials are provided			R
6A QUALITY MANAGEMENT SYSTEM PROCEDURES			
6A.4 Quality management system procedures			
There is a copy of the current version of the manufacturer's quality manual with all required information			NR
A complete list of all current quality management system procedures is included			NR
Documented procedure/s relevant to risk management planning and implementation are included			NR
6A.6 Resource management procedures			
Staff organogram is provided			NR
6A.7 Product realization procedures			
Procedures addressing planning and customer related processes are included			NR
6A.8 Design and development			
Documented procedure/s for the control of design and development changes, and change notification are included			NR
If design takes place at multiple sites, the controlling site is identified			NR

Dossier Content Requirement	Provided	Location	Abridged requirements
6A.9 Purchasing procedures			
Names and addresses of all critical subcontractors are included, where applicable			NR
Documented procedure/s relevant to the control of key suppliers including procedures for supplier evaluation and control, and verification of purchased product are included			NR
6A.10 Production and service control procedures			
Procedures documenting that production and services activities are carried out under controlled conditions are provided			*NR*
Documented procedures for the determination of batch/lot criteria are provided			NR
Batch release criteria for the product are provided			NR
6.A.12 Quality management system measurement, analysis and improvement procedures			
Documented procedure/s relevant to control of non-conforming goods including, but not limited to, procedures for complaint handling, vigilance, are included			NR
6B.9 Production and service controls information			
Full addresses and contact information for all sites undertaking manufacture of the IVD are provided			NR
A site master file, with a diagram of the floor plan, is provided			NR
A flow chart of the entire manufacturing process is included			NR
There are details of each major step (including in – process control points and final product testing and packaging) in the manufacturing process			NR
List of critical raw materials is provided			NR

Dossier Content Requirement	Provided	Location	Abridged requirements
There is an overview of verification, validation, and quality control activities for all stages of design and manufacture			NR
List of outsourced processes with direct product impact is supplied			NR
A description of any other manufacturing that occurs at each site			NR

Manufacturer Declaration:

The undersigned authorized contact person for the Manufacturer makes the following declarations on behalf of the Manufacturer and, in signing this product dossier checklist form, declares that he/she has the authority to bind the Manufacturer.

I declare that:

- I am authorized to represent the manufacturer specified in this prequalification product dossier (the "Manufacturer") for the purposes of WHO Prequalification of In Vitro Diagnostics for the product specified in this product dossier (the "Product").

- All the information provided in this product dossier is current and correct.

- This product dossier contains all the information as is prescribed in the *Prequalification of Diagnostics Programme - Instructions for Compilation of a Product Dossier* (Document PQDx_018).

- The Manufacturer will notify WHO of all changes and variations to the Product prior to implementation of the changes.

- The Manufacturer will notify WHO of any changes to the regulatory approval status for the Product, such as suspension or withdrawal of regulatory approval, in all countries of manufacture and supply.

Name of the Authorized Contact Person for the Manufacturer:_____

Signature of the Authorized Contact Person for the Manufacturer:_____

Date:_____

Please Note: The Checklist submitted to WHO must be signed and dated