



In Vitro Diagnostics Assessment Team
Prequalification Unit – Regulation and Prequalification Department

CHANGE REQUEST FORM FOR WHO PREQUALIFIED & EMERGENCY USE LISTED IN VITRO DIAGNOSTICS

DRAFT FOR COMMENT: This is a draft intended for review by Member States and all interested parties for the purpose of consultation on the draft text. The content of this document is not final, and the text may be subject to revisions before publication. The document may not be reviewed, abstracted, quoted, reproduced, transmitted, distributed, translated or adapted, in part or in whole, in any form or by any means without the permission of the World Health Organization.

This document is only applicable for reportable changes to WHO prequalified and emergency use listed in vitro diagnostic products. See WHO document *Reportable Changes to WHO Prequalified & Emergency Use Listed In Vitro diagnostics* (PQDx_121).

1. Change Request Application Information

Name(s) of product(s) affected by the change(s)	Click here to enter text.
PQDx/EUL number(s) of product(s) affected by the change(s)	Click here to enter text.
Product code(s)/catalogue number(s) affected by the change(s)	Click here to enter text.
Description of the proposed change(s)	Click here to enter text.
Manufacturer internal reference of the change(s)	Click here to enter text.
Manufacturing site(s) name(s) and address(es) for the product(s) affected by the change(s)	<input type="checkbox"/> Same as for legal manufacturer Name: Click here to enter text. Address: Click here to enter text.

2. Manufacturer Information

2.1. Legal manufacturer

Name of manufacturer	Click here to enter text.		
Manufacturer physical address	Street Name and No.: Click here to enter text.		
	City: Click here to enter text.		
	Postcode: Click here to enter text.	Country: Click here to enter text.	

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Manufacturer postal address	Street Name and No.: Click here to enter text.	
	Postal Office Box No.: Click here to enter text.	
	City: Click here to enter text.	
	Postcode: Click here to enter text.	Country: Click here to enter text.
Manufacturer telephone	Click here to enter text.	
Manufacturer e mail & web address	Click here to enter text.	
Name of parent company	Click here to enter text.	

2.2. Authorized contacts for the manufacturer¹

Name of first authorized contact	Salutation	Click here to enter text.
	First Name	Click here to enter text.
	Middle Name	Click here to enter text.
	Last Name	Click here to enter text.
Authorized contact postal address	Department: Click here to enter text.	
	Street Name and No.: Click here to enter text.	
	City: Click here to enter text.	
	Postcode: Click here to enter text.	Country: Click here to enter text.
Authorized contact telephone	Fixed line: Click here to enter text.	Mobile phone: Click here to enter text.
Authorized contact email	Click here to enter text.	
Authorized contact job title	Click here to enter text.	
Name of second authorized contact	Salutation	Click here to enter text.
	First Name	Click here to enter text.
	Second Name	Click here to enter text.
	Last Name	Click here to enter text.
Authorized contact postal address	Department: Click here to enter text.	
	Street Name and No.: Click here to enter text.	
	City: Click here to enter text.	
	Postcode: Click here to enter text.	Country: Click here to enter text.
Authorized contact telephone	Fixed line: Click here to enter text.	Mobile phone: Click here to enter text.
Authorized contact email	Click here to enter text.	
Authorized contact job title	Click here to enter text.	

3. Supporting evidence to be submitted to WHO:

The following tables provide required information (but not limited to the below mentioned documents) for the assessment of the Change Request. These lists are indicative, as it is the manufacturer's responsibility to submit all necessary information for WHO to assess the change,

¹ [The above person is authorized to represent the manufacturer for the purposes of prequalification of this product].

including any preliminary data supporting the change's compliance with WHO Prequalification requirements.

Documents referenced in L impact application columns shall be submitted for review for changes classified as Low Impact by the manufacturer or for change(s) already assessed and approved by a Recognized Authority, while documents listed in Change Request M/H Impact application columns shall be provided for changes considered Moderate/High Impact.

Required documents are marked with an (✓) where applicable. If not applicable, the manufacturer shall provide a rationale. Additional information can be found in the WHO document *Reportable Changes to WHO Prequalified & Emergency Use Listed In Vitro Diagnostics* (PQDx 121).

The required information should either be included in the table or referenced as annexes in the column titled "Summary Information/Rationale/Reference to Supporting Annexes/Justification if not applicable."

WHO reserves the right to request additional documents during the review of the submission each time deemed necessary.

3.1. General information on the change(s)

	Information to be submitted as applicable	Change Request L Impact application	Change Request M/H Impact application	Summary information/Rationale/Reference to Supporting Annexes/Justification if not applicable
1.	Detailed description of the change	✓	✓	Click here to enter text.
2.	Reasons for the change	✓	✓	Click here to enter text.
3.	Impact categorization as per internal assessment and justification	✓	✓	<input type="checkbox"/> L Impact <input type="checkbox"/> M/H Impact
4.	Change stringently assessed by a Recognized National Regulatory Authority (NRA) as defined in the WHO document <i>Abridged prequalification assessment: prequalification of in vitro diagnostics</i> (PQDx_173), the change request may be accepted upon screening. In this	✓	✓	<input type="checkbox"/> Yes <input type="checkbox"/> No Please specify: Click here to enter text.

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	case, the submission requirements for low impact change would apply (See PQDx 119).			
5.	Recognized NRA Stringent Assessment Report of the change and updated certificate of approval	✓ This is required only if the change has been assessed and approved by an NRA. This is also a prerequisite if the product has been prequalified through an abridged assessment. If the manufacturer can provide objective evidence that the exact same proposed high/moderate impact change has previously undergone stringent assessment and approval by a Recognized NRA.		
6.	Section(s) of the Product Dossier that were or need to be updated. Please indicate which sections	✓	✓	Click here to enter text.
7.	Risk assessment of the submitted change(s) and its/their impact (Risks at each stage of the product lifecycle and impact on products, processes, operators, users, patients and third parties assessed and overall risk)	✓	✓	
8.	Change control timelines with details on finalized and planned activities including QMS procedures, Verification & Validation, QC updates and PMS	✓	✓	
9.	Change control records based on manufacturer's change control procedure		✓	

3.2. Evidence to support the control of the impact of the change on the QMS and the manufacturing process

	Information to be submitted as applicable	Change Request L Impact application	Change Request M/H Impact application	Summary information/Rationale/Reference to Supporting annexes/Justification if not applicable
10.	Identification of relevant changes to QMS	✓	✓	
11.	Identification of relevant changes to facilities, equipment, processes, workflows and manufacturing procedures of the product or its accessories, components or subparts	✓	✓	
12.	Verification/Validation protocols		✓	
13.	Verification/Validation report		✓	

3.3. Evidence to support the control of the impact of the change on purchasing

	Information to be submitted as applicable	Change Request L impact application	Change Request M/H Impact application	Summary information/Rationale/Reference to Supporting Annexes/ Justification if not applicable
14.	Identification of relevant changes to critical components or services or suppliers or supplier control		✓	
15.	Supplier approval/monitoring records with relevant information of the purchased material/service		✓	
16.	Certificate(s) of Analysis and/or of Conformity of the material with relevant information, including technical specifications		✓	

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17.	In the case of critical suppliers: quality agreements and latest audit reports		✓	
18.	Valid ISO Certification of suppliers/manufacturers / regulatory QMS certificate or WHO inspection		✓	
19.	If applicable, valid product approval certificates issued by a Recognized National Regulatory Authority (NRA) as defined in the WHO document <i>Abridged prequalification assessment: prequalification of in vitro diagnostics</i> (PQDx_173)		✓	
20.	Valid special processes certification of the manufacturer/supplier linked with the material concerned		✓	

3.4. Evidence to support the control of the impact of the change on the design that could affect the performance of the finished product

	Information to be submitted as applicable	Change Request L Impact application	Change Request M/H Impact application	Summary information/Rationale/Reference to Supporting Annexes/ Justification if not applicable
21.	Protocols and reports of analytical performance as per the relevant WHO requirements and TSS (e.g., sensitivity, specificity, reproducibility, repeatability, robustness)		✓	
22.	Protocols and reports of stability studies		✓	

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	(Shipping, in-use, shelf-life)			
23.	Clinical Performance evaluation protocols and reports, including usability studies when applicable		✓	
24.	Updated Labelling and Instruction for use	✓	✓	
25.	Updated product training and information documentation		✓	
26.	Updated PMS process		✓	

3.5. Other evidence supporting the control of the change

	Information to be submitted as applicable	Change Request L Impact application	Change Request M/H Impact application	Summary information/Rationale/Reference to Supporting Annexes/ Justification if not applicable
27.	Please add rows as necessary...			
28.	...			

4. Manufacturer Declaration

The undersigned duly authorized representative of the Manufacturer makes the following declarations on behalf of the Manufacturer and, in signing this change request form, declares that he/she has the power and authority to bind the Manufacturer.

I declare that:

- I am authorized to represent the manufacturer specified in this change request form (the "Manufacturer") for the purposes of WHO diagnostics prequalification of the product specified in this application form (the "Product").
- All the information provided in this form is current, complete and correct.
- Any changes to the information provided in this form will be readily communicated by the Manufacturer to WHO.
- The Manufacturer holds data in support of all claims made in this change request form.
- The Manufacturer understands and agrees that the purpose of the WHO prequalification of IVDs is to provide guidance to interested UN agencies and WHO Member States in their procurement decisions. In this regard, the results of the prequalification assessment, the participation in the WHO prequalification assessment process, the inclusion of any product in the WHO list of prequalified IVDs and/or the WHO name and emblem, may not be used by manufacturers or any other party for commercial and/or promotional purposes.
- The Manufacturer understands and agrees that the validity of the prequalification status is dependent on the fulfilment of post-qualification requirements including:
 - prequalification commitments;
 - annual reporting;
 - reporting of changes;
 - post-market surveillance obligations;
 - receiving re-inspection; and
 - ongoing compliance with WHO prequalification technical specifications.

Name of the Duly Authorized Representative of the Manufacturer: [Click here to enter text.](#)

Signature of the Duly Authorized Representative of the Manufacturer: _____

Date: DD/MM/YYYY