

**CHANGE REPORT FORM FOR A WHO PREQUALIFIED IN VITRO DIAGNOSTIC MEDICAL DEVICE**

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| --- | --- |
| Application Number(s):  [indicate all of the PQDx numbers affected by the changes (s)] | PQDx |
| Manufacturer name: |  |
| Product name and code(s): |  |
| Summary of changes  (200 character limit) |  |

This document is only applicable for reportable changes to a prequalified in vitro diagnostic medical device. See WHO document Reportable Changes to a WHO prequalified in vitro diagnostic medical device (document PQDx\_121).

# Manufacturer Information

## Manufacturer

|  |  |
| --- | --- |
| * + 1. *Name of manufacturer* |  |
| * + 1. *Manufacturer physical address* | *Street Name and No.:* |
| *City:* |
| *Postcode:* |
| *Country:* |
| * + 1. *Name of parent company* |  |

## Authorized contacts for the manufacturer[[1]](#footnote-1)

|  |  |
| --- | --- |
| * + 1. ***Name of key authorized contact*** |  |
| * + 1. *Authorized contact telephone* | *Fixed line:* |
| *Mobile/Cell phone:* |
| * + 1. *Authorized contact email* |  |
| * + 1. ***Name of second authorized contact*** |  |
| * + 1. *Authorized contact telephone* | *Fixed line:* |
| *Mobile/Cell phone:* |
| * + 1. *Authorized contact email* |  |

# Prequalified Product Information[[2]](#footnote-2)

|  |  |
| --- | --- |
| * + 1. PQDx number | *PQDx* |
| * + 1. *Product name* |  |
| * + 1. *Product code(s)* |  |
| * + 1. *Prequalified Regulatory  version* |  |
| * + 1. *Manufacturing site name and address* | *Name:* |
| *Street Name and No.:* |
| *City:* |
| *Postcode:* |
| *Country:* |

# Change Information

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|  | **Types of reportable changes** |
|  | Changes to the manufacturing process |
|  | Physical move/relocation of finished product manufacturing, assembling or other processing equipment from one location to a different location or; addition of a new facility (manufacturing facility, warehouse, etc.) within the same location. |
|  | Change in the manufacturing process such as the introduction of new equipment or change in workflow. |
|  | Changes to the manufacturing quality control procedures, such as the methods, tests or procedures used to control the quality of the materials or the product. |
|  | Removal of test acceptance criteria for in-process and finished product. Removal of in-process inspections or final inspections without replacement of these activities. |
|  | Addition of in-process inspection steps in response to post-market product issues. |
|  | Change of a supplier, or sub-tier supplier, of reagents, antigens, antibodies, preservatives, anticoagulants, primers or solid phase. |
|  | Move of manufacturing, processing or packaging from a supplier to the manufacturer’s facility. |
|  | Move of manufacturing, processing or packaging from the manufacturer’s facility to a supplier. |
|  | **‎**Design changes and changes to intended use |
|  | A change to the reagent volume or specimen volume required to perform the test. |
|  | A change to the reading period (minimum or maximum). |
|  | The acceptability of new anticoagulants for plasma specimens. |
|  | A change to the manufacturer-defined automation process (including change to a new smaller/larger model if the IVD is an instrument) or the change from a manual procedure to an automated procedure for use. |
|  | A change to the operating principle. |
|  | Changes to materials/components supplied with the IVD (e.g. introduction of new ancillary reagents such as quality control reagents). |
|  | A change to the function of the product (e.g. screening, monitoring, diagnosis or aid to diagnosis, staging or aid to staging of disease, prediction, self-testing). |
|  | A change to the specific disorder, condition or risk factor of interest that the IVD is intended to detect, define or differentiate. |
|  | A change in performance or design specifications. |
|  | A change from qualitative to quantitative test results or vice versa. |
|  | Addition or removal of a specimen type (e.g. serum, plasma, whole blood, oral fluid, sputum, urine, dried blood spot). |
|  | A change to the intended testing population including any new or extended use (e.g. addition of neonates, antenatal women). |
|  | An addition or deletion of a contraindication for the device. |
|  | A change in the stability data resulting in a change to the period used to establish the expiry date of the IVD. |
|  | Changes to the materials supplied with the IVD (e.g. accessories such as lancets). |
|  | Changes in materials/components |
|  | Changes to the formulation of reagents in the assay that result in a change (either increase or decrease) to the stability /shelf-life claims. |
|  | Changes in the conjugate or substrates that change the intended use. |
|  | Changes in specimen preparation such as a change in nucleic acid extraction method. |
|  | The addition or change of a preservative to a reagent of the test kit. |
|  | Changes to the source (supplier) or processing of biological materials. |
|  | Changes from liquid to lyophilized reagents or vice versa. |
|  | Changes to materials/components that necessitate testing of additional clinical specimens, or retesting of original specimens, to determine performance characteristics of the IVD. |
|  | Changes to the materials/components of an IVD that result in a change to the operating principle of the product. |
|  | Changes to materials/components that potentially affect the operating procedure of an IVD including changes in reaction components or materials such as calibration materials, or changes in methods such as specimen pre-treatment, incubation times and operating temperatures. |
|  | Changes in power supply requirements. |
|  | Changes to labelling |
|  | All changes to labelling with exception of those listed in **Annex 3: Examples of non-reportable changes** are those made to:   * clarify labelling statement (e.g. clarifying instructions to make the device easier or safer to use) without changing the procedure; * correct errors (e.g. typographical errors or numerical errors); and/or * include additional languages. |
|  | ‎Changes to a product’s software |
|  | A software change that impacts the control of the product and may alter the reporting result that is used in the diagnosis or other function. |
|  | A software change that modifies an algorithm impacting the test result. |
|  | A software change that impacts the way data are read or interpreted by the user, such that the diagnosis or other function may be altered when compared to the previous version of the software. |
|  | A software change that replaces previously required user input. |
|  | A software change to correct an error that presents a safety risk to the patient. |
|  | Addition of a new feature to the software that may affect the diagnosis or other software-driven function. |
|  | A software change that incorporates a change to the operating system on which the software runs. |
|  | Changes to the QMS |
|  | Changes in the ISO 13485 certification status of the manufacturer, of the prequalified IVD, such as suspension of the ISO 13485 certificate, obtaining a new certification, or change in the scope of certification. |
|  | Change in Notified Body or certification body. |
|  | Changes to the legal manufacturer including: |
|  | Change of ownership |
|  | Change of legal entity status (e.g. Ltd, SA, etc.) |
|  | Change of name and/or address. |
|  | Change to the regulatory status |
|  | Change in the regulatory status of the prequalified IVD in any of the member nations or regions of the International Medical Device Regulators Forum (IMDRF). (e.g. licence suspension in Canada, receipt of a Warning Letter from the US FDA, suspension of ARTG registration in Australia, or suspension of a CE mark certification in the European Union.) |
|  | Administrative changes |
|  | Changes only to the product name. |
|  | Changes only to the product code(s). |
|  | Changes only to the manufacturer name. |

# Attachments to the change notification form

Below is a list of attachments to this form. The requested attachments must be clearly divided into sections, as per the below list, and the pages of each section should be numbered.

|  |  |  |
| --- | --- | --- |
| Section | Attachment content | Location Page - Page |
| 1. | A description of the product. |  |
| 2. | A detailed description of the planned changes as compared to the prequalified product (illustrative figures should also be included, where possible). |  |
| 3. | The reasons for the changes, including any information on adverse events or field failures that occurred in the original prequalified product. |  |
| 5. | A summary of the data supporting the change (a summary of key results), including: |  |
| 5.1. | A summary of the procedures established for the identification, documentation, verification or validation, review, and approval of the changes. |  |
| 5.2. | The statistical rationale for the sampling method used for the verification of the changed process. |  |
| 5.4. | A summary of the completed verification and/or validation studies that demonstrate that the manufacturing change can be made without significantly changing the quality, safety and performance of the changed product. This should include: |  |
| 5.4.1. | A description of the acceptance criteria. |  |
| 5.4.2. | The test data analysis (including statistical methods). |  |
| 5.4.3. | The statistical rationale for sample sizes. |  |
| 5.4.4. | A list of deviations that occurred and detailed description of how each deviation was resolved. |  |
| 5.4.5. | A determination of the impact of deviations on the final results. |  |
| 5.4.6. | An explanation of how change control procedures were implemented, including the modifications of the manufacturing or quality control instructions or manufacturing specifications. |  |
| 5.5. | A detailed risk assessment of the changes as related to safety and performance of the test. |  |
| 6. | The identification of the manufacturing site(s) where the changes will be implemented. |  |
| 8. | If applicable, the amended instructions for use with the changes highlighted. |  |
| 9. | Any action planned to inform the end user about the changes in the product (instructions for use, retraining, etc.). |  |
| 10. | A plan for follow up of the changed product (post market surveillance, end user feedback, etc.). |  |
| 11. | Any other relevant data supporting the change. |  |

In addition to the requirements listed above, certain changes require supplementary information in the submission to WHO.

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| Physical move/relocation of finished product manufacturing, assembling or other processing equipment from one location to a different location or; addition of a new facility (manufacturing facility, warehouse, etc.) within the same location. | Location Page- Page |
| Information required:   * address of the new site; * a description of manufacturing activity planned for the new site and original site (if applicable); * the dates of technology transfer to the new site; * the validation plan for the new site; * studies (including protocols and comprehensive study reports) demonstrating substantial equivalence between the product manufactured at the new site(s) and the prequalified product and evidence that the results have been considered acceptable by senior management (signature and date); * the ISO 13485:2003 or 2016 certificate; * the ISO 13485:2003 or 2016 full audit report for the new site(s); and * in case of instrument based assays, whether the reagents and/or instruments will be manufactured in the new site. |  |
| Change in the manufacturing process such as the introduction of new equipment or change in workflow |  |
| Information required:   * a description of how the manufacturing process that is intended to be changed will be monitored and controlled. * validation of processes, qualification of new equipment installation; * validation of product performance at the new site; * a summary of the new manufacturing process outlining the differences between the old and the new process; and * the dates of anticipated change implementation. |  |
| Changes in suppliers of components or raw materials that are critical to the product performance or the use of a new contractor for a manufacturing process or quality control testing |  |
| Information required:   * A summary of purchasing control procedures implemented to evaluate a new supplier or contractor. |  |

# Submission of the Change Report Form and attachments

An electronic copy of the completed Change Report Form and all of the above listed attachments must be submitted in CD or DVD and posted to:

WHO Prequalification of Diagnostics

World Health Organization

20 Avenue Appia

CH-1211, Geneva 27

Switzerland

# Manufacturer Declaration

The undersigned key authorized representative of the Manufacturer makes the following declarations on behalf of the Manufacturer and, in signing this 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 form (the "Manufacturer") for the purposes of this change report form of the product specified in (the "Prequalified Product Information").
* All information requested in Section 4 of this form has been submitted as an attachment to this form.
* All the information provided in this form and its attachments is current and correct.

Name of the Key Authorized Contact Person for the Manufacturer:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature of the Key Authorized Contact Person for the Manufacturer:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

1. If the authorized contacts for the manufacturer differ from those designated in the application form, a signed letter from the manufacturer stating that the above two people are authorized to represent the manufacturer for the purposes of prequalification should be submitted. [↑](#footnote-ref-1)
2. As per the Prequalification Public Report [↑](#footnote-ref-2)