Application form - Conformation method

*v.3 2022-06-21*

MicroVal validation / certification of an alternative microbiological confirmation method   
(ISO 16140-6)

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| Please send this application form to: [*microval@nen.nl*](mailto:microval@nen.nl)or  *MicroVal, P.O.Box 5059 NL 2600 GB Delft* | | To be completed by MicroVal Secretariat | |
| Registration No. | Date received |
| **1** | **Alternative confirmation method** | | |
|  | Name  Product technology  (when applicable: e.g., PCR device)  Special equipment required yes/no  Software version?  Analytical parameters / Microorganisms  Reference method (ISO or other)  Target confirmation step  Scope (media from which the confirmation can start)  Kit insert version number | -  -  -  - -  - - -  -  - | |
| Has this method been validated before? | **□** No **□** Yes, by \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  (please add relevant information) | |
| **2.** | **Manufacturer / distributor** | | |
|  | Company name  Contact name and title  Address  Phone number  E-mail  Number of employees | -  -  -  -  -  - | |

|  |  |  |
| --- | --- | --- |
| **3.** | **Expert lab** | |
| Name  Contact | -  - |
| If you have not yet selected a lab, please check the list of MicroVal Expert Labs [here](http://microval.org/en/certification-procedure/4-2which-laboratories-can-help-me/). | |
| **4.** | **Production site** | |
| Company name  Contact name and title  Address  Phone number  E-mail  Number of employees | **-**  **-**  **-**  **-**  **-**  **-** |
| **5.** | **Quality Management System at the production site** | |
| - ISO 9001  - ISO 13485  - Other: | **□** No **□** Yes\*  **□** No **□** Yes\*  **□** No **□** Yes\*, namely: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  \* Please add a copy of the certificate, including the most recent audit report |
| **6.** | **Certification Body** | |
| Company name  Contact  Phone number  Email | LRQA Nederland B.V.  Mr. Peter Vizee  +31 10 899 73 00  [Microval@nen.nl](mailto:Microval@nen.nl) / [peter.vizee@lrqa.com](mailto:peter.vizee@lrqa.com) |

Date: ………………………………….

Company: ……………………………........

Name: …………………………………..

Signature: …………………………………..

Please complete the enclosed kit insert evaluation.

## Kit Insert / User Manual Evaluation

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **1.** | **Intended use** |  |  | Remarks |
| Does the kit insert identify intended use? | **□** Yes | **□** No |  |
| **2.** | **Identification** | | | |
| Is the version of kit insert identifiable? | **□** Yes | **□** No |  |
| **3.** | **Applicability** | | | |
| Does the kit insert identify the target analytes and media that the kit is designed for, and include precautionary statements on potential interferences and other known limitations of the test if applicable? | **□** Yes | **□** No |  |
| Does the kit take into consideration the pre-treatment of samples, e.g. based on ISO 6887 series? | **□** Yes | **□** No |  |
| **4.** | **Interpretation Criteria** | | | |
| Does the kit insert explain how the test is interpreted? | **□** Yes | **□** No |  |
| **5.** | **Instructions** | | | |
| Does the kit insert describe test sample preparations and handling or any analyte extraction that is required? | **□** Yes | **□** No |  |
| Does the kit insert include complete instructions on how to conduct the test? | **□** Yes | **□** No |  |
| Does the kit insert describe the use of any internal or external quality control features? | **□** Yes | **□** No |  |
| Does the kit insert state which part of the method is MicroVal certified? | **□** Yes | **□** No |  |
| **6.** | **Shelf Life** |  |  |  |
| Does the labelling include information about the shelf life and storage conditions for the kit? | **□** Yes | **□** No |  |
| **7.** | **Technical Assistance** | | | |
| Does the kit insert provide information (Website, email, telephone and FAX numbers) where users can obtain technical assistance? | **□** Yes | **□** No |  |