



Validation of analysis methods
NF148 – Application to water

Certificate

Certificate No.: **DTV 41/01- 12/19**
Renewal decision dated: **02-10-2023**
Expiry date: **04-12-2027**

The Company:

DIATHEVA S.R.L
Via Sant'Anna 131-135
61030 Cartoceto (PU) - Italie

Is authorized to affix the NF VALIDATION mark on the alternative method cited below, in accordance with the NF VALIDATION general rules and the certification rules NF148 - Validation of analysis methods (Application to water):

DI-Check *Legionella pneumophila*

Validated for detection and quantification of *Legionella pneumophila*

Technical sheet reference's

IFU	Part Numbers	Version
DNApure Water Isolation kit	MBK0080 - 100 extractions	Ver.02-05/2019
DI-Check Legionella pneumophila kit	MBK0081 - 100 reactions	Ver. 02-0419

This decision attests that the analysis method has been assessed by AFNOR Certification and found to conform to the standards cited in page 2/2 and complementary requirements, as specified in the certification reference document. The **principal certified characteristics** are the “analytical performances” as defined in the associated validation study summarized report (relative sensitivity and linearity, detection limit...), available on the certification dedicated website <http://nf-validation.org/en>.

This certificate supersedes all previous certificates (last version dated 17-07-2020). This NF VALIDATION certificate, included 2 pages, is valid until **4th December 2027**. It is subject to the results obtained upon regular controls carried out by AFNOR Certification. Appropriate decision is made by AFNOR Certification in accordance with the NF VALIDATION general rules and certification rules NF148 - Validation of alternative analysis methods (Application to water).




Managing Director
Julien NIZRI



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The alternative analysis method:

DI-Check *Legionella pneumophila*

Validated for detection and quantification of *Legionella pneumophila*

Manufactured by:

DIATHEVA S.R.L
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61030 Cartoceto (PU) – Italy

Has been certified according to the reference documents and the application scope specified here after:

Validation protocol	NF VALIDATION - Validation of analysis methods: Application to water microbiology. Validation protocol for commercial methods of detection and quantification of <i>Legionella</i> and <i>Legionella pneumophila</i> by concentration and gene amplification by polymerase chain reaction (PCR). Revision 3 (September 2015).
Reference method(s)	NF T90-471 (June 2015): Water quality - Detection and quantification of <i>Legionella</i> and/or <i>Legionella pneumophila</i> by concentration and genic amplification by real time polymerase chain reaction (qPCR). ISO/TS 12869 (April 2019): Water quality - Detection and quantification of <i>Legionella</i> spp. and/or <i>Legionella pneumophila</i> by concentration and genic amplification by quantitative polymerase chain reaction (qPCR).
Scope	Sampling all types of waters.
Restriction(s)	None.
Warning	None.
Other informations	The scope includes the use of the instruments: Qiagen Rotor-Gene (2Plex – 5Plex), Applied Biosystems QuantStudio (QS3 et QS5) and BIO-RAD CFX (CFX96 et CFX96 Deep Well Touch) with the DI-Check Analysis software for <i>L. pneumophila</i> version 2.2.

Please send any queries concerning the performances of the certified alternative method to AFNOR Certification.

You may download the validation study **summarized report** on <http://nf-validation.afnor.org/en>.