

EC CERTIFICATE

Number: 2114129CE01

Full Quality Assurance System

Directive 98/79/EC on In Vitro Diagnostic Medical Devices, Annex IV excluding (4,6)
(List A, B and devices for self-testing)

Manufacturer:

IQ Products B.V.

Rozenburglaan 13a
9727 DL Groningen
The Netherlands

For the product category(ies)

CMV pp65 detection kits

DEKRA grants the right to use the EC Notified Body Identification Number illustrated below to accompany the CE Marking of Conformity on the products concerned conforming to the required Technical Documentation and meeting the provisions of the EC-Directive which apply to them:

0344

Documents, that form the basis of this certificate:

Certification Notice 2114129CN, initially dated 10 April 2008

DEKRA hereby declares that the above mentioned manufacturer fulfils the relevant provisions of 'Besluit in-vitro diagnostica', the Dutch transposition of the Council Directive 98/79/EC of October 27, 1998 concerning In vitro diagnostic medical devices, including all subsequent amendments. The manufacturer has implemented a quality assurance system for design, manufacture and final inspection for the above mentioned product category in accordance to the provisions of Annex IV of Council Directive 98/79/EC of October 27, 1998 and is subject to periodical surveillance. For placing on the market of List A devices an additional EC design examination certificate according to Annex IV (4) is mandatory.

The necessary information related to the quality assurance system of the manufacturer, including facilities and the reference to the relevant documentation, of the products concerned and the assessments performed, are stated in the Certification Notice which forms an integrative part of this certificate.

This certificate is valid until: 1 February 2022

Issued for the first time: 10 April 2008

Reissued: 1 February 2019

DEKRA Certification B.V.


B.T.M. Hofius
Managing Director


H. van. Vugt
Certification Manager

© Integral publication of this certificate and adjoining reports is allowed

DEKRA Certification B.V. is Notified Body with ID no 0344

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The undersigned, Karen Astrid Verkerk, civil-law notary at Arnhem, The Netherlands, certifies that the signatures on the reverse side of this certificate are the genuine signatures of Mr B.T.M. Holtus, Managing Director and Mr. J.A. van Vugt, Certification Manager of DEKRA Certification B.V.

Arnhem, January 28, 2019



Karen A. Verkerk



APOSTILLE

(Convention de La Haye du 5 octobre 1961)

1. Country: THE NETHERLANDS
This public document
2. has been signed by **mr. K.A. Verkerk**
3. acting in the capacity of notary at Arnhem
4. bears the seal/stamp of aforesaid notary

Certified

5. in Arnhem
6. on 30-01-2019
7. by the registrar of the district court of Gelderland
8. no. 19-240
9. Seal/stamp:
10. Signature:

O. Ekizkaya

