EC CERTIFICATE

Number: 2112558CE02

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:

DiaSorin Molecular LLC

11331 Valley View Street
Cypress CA 90630
United States Of America

For the product category(ies)

Nucleic Acid Based assays, related components and CMV Quantitation Standards for the Detection of Cytomegalovirus DNA in Humans for monitoring disease progress of CMV infected patients

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 2112558CN, initially dated 30 January 2008
Addendum, initially dated 26 October 2011

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 September 2019
Issued for the first time: 26 October 2011
Reissued: 1 September 2016

DEKRA Certification B.V.

drs. G.J. Zoetbrood
Managing Director

ing. A.A.M. Laan
Certification Manager

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

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ADDENDUM

Belonging to certificate: 2112558CE02

CE MARKING OF CONFORMITY
IN VITRO DIAGNOSTIC MEDICAL DEVICES

Nucleic Acid Based assays, related components and CMV Quantitation Standards for the Detection of Cytomegalovirus DNA in Humans for monitoring disease progress of CMV infected patients

Issued to:

DiaSorin Molecular LLC
11331 Valley View Street
Cypress CA 90630
United States Of America

This certificate covers the following product(s):

REF MOL2200 Simplexa™ CMV assay
REF MOL2210 Simplexa™ CMV Quantitation Standards

Initial date: 26 October 2011

DEKRA Certification B.V.

drs. G.J. Zoetbrood
Managing Director

ing. A.A.M. Laan
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