EC CERTIFICATE

Number: 2085393CE01

Production Quality Assurance

Directive 93/42/EEC on Medical devices, Annex V
(Devices in Class IIa, IIb or III)

Manufacturer:

DiagnOptics Technologies B.V.

Aarhusweg 4-9
9723 JJ Groningen
The Netherlands

For the product category(ies)

Analyzer for Advanced Glycation Endproducts (AGE) by means of skin auto fluorescence

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 2085393CN, initially dated 27 April 2006
Addendum, initially dated 27 April 2006

DEKRA hereby declares that the above mentioned manufacturer fulfils the relevant provisions of 'Besluit Medische Hulpmiddelen', the Dutch transposition of the Council Directive 93/42/EEC of June 14, 1993 concerning Medical devices, including all subsequent amendments. The manufacturer has implemented a quality assurance system for the manufacture and final inspection for the above mentioned product category in accordance to the provisions of Annex V of Council Directive 93/42/EEC of June 14, 1993 and is subject to periodical surveillance. For placing on the market of Class III or Class IIb devices an additional EC type-examination certificate according to Annex III 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 May 2023
Issued for the first time: 27 April 2006
Reissued: 1 May 2018

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

DEKRA Certification B.V. Meander 1051, 6825 MJ Arnhem P.O. Box 5185, 6802 ED Arnhem, The Netherlands
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ADDENDUM

Belonging to certificate: 2085393CE01

CE MARKING OF CONFORMITY
MEDICAL DEVICES

Analyzer for Advanced Glycation Endproducts (AGE) by means of skin auto fluorescence

Issued to:

DiagnOptics Technologies B.V.
Aarhusweg 4-9
9723 JJ Groningen
The Netherlands

This certificate covers the following product(s):

AGE Reader MU

Initial date: 27 April 2006

DEKRA Certification B.V.

drs. G.J. Zoetbrood
Managing Director

ing. A.A.M. Laan
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