

CERTIFICATE

Number: 2085393CE02

CE MARKING OF CONFORMITY MEDICAL DEVICES

Issued to:

DiagnOptics Technologies B.V.

L.J. Zielstraweg 1
9713 GX Groningen
The Netherlands

For the product category:

Analyzer of Advanced Glycation Endproducts (AGE) by means of skin auto fluorescence to assess the risk of having (pre)diabetes

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 14 November 2011

DEKRA hereby declares that the above mentioned manufacturer fulfils the relevant provisions of 'Besluit Medische Hulpmiddelen', the Dutch transposition of the Directive 93/42/EEC of June 14, 1993 concerning Medical devices, including all subsequent amendments, and that for the above mentioned product category the Conformity Assessment Procedure Annex V in combination with Annex VII for class IIa products, is executed by the Manufacturer in accordance with the provisions of the Council Directive 93/42/EEC of June 14, 1993. The necessary information 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 2015
Issued for the first time: 14 November 2011
Reissued: 1 May 2012

DEKRA Certification B.V.



drs. G.J. Zoetbrood
Managing Director



ing. A.A.M. Laan
Certification Manager

© Integral publication of this certificate and adjoining reports is allowed

All testing, inspection, auditing and certification activities of the former KEMA Quality are an integral part of the DEKRA Certification Group.

ADDENDUM

Belonging to certificate: 2085393CE02

1/1

CE MARKING OF CONFORMITY MEDICAL DEVICES

Analyzer of Advanced Glycation Endproducts (AGE) by means of skin auto fluorescence to assess the risk of having (pre)diabetes

Issued to:

DiagnOptics Technologies B.V.
L.J. Zielstraweg 1
9713 GX Groningen
The Netherlands

This certificate covers the following product(s):

Diab-spot

Initial date: 14 November 2011

DEKRA Certification B.V.

A blue ink signature of G.J. Zoetbrood, written in a cursive style.

drs. G.J. Zoetbrood
Managing Director

A blue ink signature of A.A.M. Laan, written in a cursive style.

ing. A.A.M. Laan
Certification Manager

© Integral publication of this certificate and adjoining reports is allowed

All testing, inspection, auditing and certification activities of the former KEMA Quality are an integral part of the DEKRA Certification Group.