

CERTIFICATE

Number: 2144567CE01

CE MARKING OF CONFORMITY IN VITRO DIAGNOSTIC MEDICAL DEVICES

Issued to:

NORDITALIA ELETTROMEDICALI S.R.L.

Via Colli Storici 215

Brescia

25015 San Martino Della Battaglia (BS)

Italy

For the product category (Annex II, list B):

Blood glucose measuring systems for self testing

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 2144567CN, initially dated 20 July 2011

Addendum, initially dated 20 July 2011

DEKRA hereby declares that the above mentioned manufacturer fulfils the relevant provisions of 'Besluit in-vitro diagnostica', the Dutch transposition of the Directive 98/79/EC of October 27, 1998 concerning In vitro diagnostic medical devices, including all subsequent amendments, and that for the above mentioned product category the Conformity Assessment Procedure Annex VII for class Annex II, list B products, is executed by the Manufacturer in accordance with the provisions of the Council Directive 98/79/EC of October 27, 1998. 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 August 2014

Issued for the first time: 20 July 2011

DEKRA Certification B.V.



drs. G.J. Zoetbrood
Managing Director



ing. A.A.M. Laan
Certification Manager

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ADDENDUM

Belonging to certificate: 2144567CE01

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CE MARKING OF CONFORMITY IN VITRO DIAGNOSTIC MEDICAL DEVICES

Blood glucose measuring systems for self testing

Issued to:

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This certificate covers the following product(s):

- glucoEASY Blood Glucose Monitoring System (including Blood Glucose Meter, Blood Glucose Test Strips and Control Solution)
- glucoEASY Plus Blood Glucose Monitoring System (including Blood Glucose Meter, Blood Glucose Test Strips and Control Solution)

Initial date: 20 July 2011

DEKRA Certification B.V.

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

drs. G.J. Zoetbrood
Managing Director

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

ing. A.A.M. Laan
Certification Manager

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