EC CERTIFICATE

Number: 2094844CE03

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:

Biochemical Systems International S.p.A

Localita Palazzo del Pero 23
52100 Arezzo
Italy

For the product category(ies)

Blood glucose measuring systems for self testing and Lipid Metabolism Monitoring 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 2094844CN, initially dated 15 February 2007
Addendum, initially dated 13 July 2012

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: 26 May 2025
Issued for the first time: 13 July 2012
Reissued: 11 March 2022

DEKRA Certification B.V.

B.T.M. Holtus
Managing Director

J.A. van Vugt
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: 2094844CE03

CE MARKING OF CONFORMITY
IN VITRO DIAGNOSTIC MEDICAL DEVICES

Blood glucose measuring systems for self testing and Lipid Metabolism Monitoring Systems for self-testing.

Issued to:

Biochemical Systems International S.p.A
Localita Palazzo del Pero 23
52100 Arezzo
Italy

This certificate covers the following product(s):

multiCare-in®
Visual® Cholesterol
OGCare
LUX System
glusys®
Aria

Initial date: 13 July 2012
Revision date: 11 March 2022

DEKRA Certification B.V.

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