

# CERTIFICATE

Number: 2094844CE03

## CE MARKING OF CONFORMITY IN VITRO DIAGNOSTIC MEDICAL DEVICES

Issued to:

**Biochemical Systems International Srl**

Via G. Ferraris 220

52100 Arezzo

Italy

For the product category (Annex II List B):

**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 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 IV 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 March 2016

Issued for the first time: 13 July 2012

Reissued: 1 March 2013

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: 2094844CE03

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## CE MARKING OF CONFORMITY IN VITRO DIAGNOSTIC MEDICAL DEVICES

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

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### **Biochemical Systems International Srl**

**Via G. Ferraris 220  
52100 Arezzo  
Italy**

This certificate covers the following product(s):

- " multiCare®
- " multiCare-in®
- " GLUCOVAL®
- " Domino Mobile®
- " Med-Care®
- " Blue Care®
- " Visual®
- " BSICare®

Initial date: 13 July 2012

Revision date: 1 March 2013

DEKRA Certification B.V.

A blue ink signature of drs. G.J. Zoetbrood.

drs. G.J. Zoetbrood  
Managing Director

A blue ink signature of ing. A.A.M. Laan.

ing. A.A.M. Laan  
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