

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

Località 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:

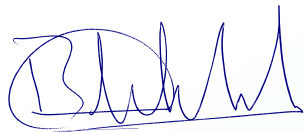
Certification Notice 2094844CN, initially dated 15 February 2007 Addendum, initially dated 13 July 2012

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: 1 March 2022
Issued for the first time: 13 July 2012
Revised: 16 May 2018
Reissued: 1 March 2019

DEKRA Certification B.V.



B.T.M. Holtus
Managing Director



J.A. van Vugt
Certification Manager

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DEKRA Certification B.V. is Notified Body with ID no 0344

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ADDENDUM

Belonging to certificate: 2094844CE03

1/1

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

**Località Palazzo del Pero 23
52100 Arezzo
Italy**

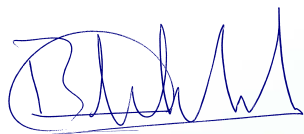
This certificate covers the following product(s):

multiCare®
multiCare-in®
Blue Care®
Visual®
OGCare
LUX System
glusys®

Initial date: 13 July 2012

Revision date: 1 March 2019

DEKRA Certification B.V.

A blue ink signature of B.T.M. Holtus, consisting of stylized, overlapping loops and lines.

B.T.M. Holtus
Managing Director

A blue ink signature of J.A. van Vugt, featuring a large, flowing initial 'J' followed by the name 'A. van Vugt' in a cursive script.

J.A. van Vugt
Certification Manager

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Biochemical Systems International S.p.A.

SEDE LEGALE

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Cap. Soc € 101.200 i.v. - C.F. e R.I. di Mi: 01736580513
P.IVA: IT01736580513 - N. REA: MI - 2509418

www.biosys.it - biosys@biosys.it - PEC: bsisrl@arubapec.it

UNITÀ LOCALI

Sede Operativa:

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Divisione Strumentazione:

Via B. Buozzi, 253 - 50013 Campi Bisenzio (FI) - Italia
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Declaration of conformity

Applicable Council Directives
Standard to which conformity is declared
Classification (IVDD 98/79/EC)

IVDD 98/79/EC
EN ISO 15197:2015 (only for glucose)
IVD, Self-testing
For glucose only: list B
Annex IV, section 3

Conformity assessment Route

Product Name

3820001/3820001 E – LUX Meter for determination of lipid profile, hemoglobin and glucose
3820300 – LUX Lipid Profile Strips 10pcs
3820310 – LUX Hemoglobin Strips 10pcs
3820380 – LUX Glucose Strips 50pcs
3820301 – Control solution TC/TG/HDL 3x2 ml
3820302 – Control solution HGB 1x2 ml
3820303 – Control solution GLC 1x2 ml
3820100 – Lux pipette 7 uL for hemoglobin
3820201 – Lux pipette 15 uL for lipid profile
AC1005/50 – Pipette tips – box of 50 pcs
3830001/3830001 E/3830001+CD – Multicare IN meter for determination of cholesterol, triglycerides and glucose
3830260 – Multicare IN cholesterol strips 25pcs
3830261 – Multicare IN cholesterol strips 5pcs
3830270 – Multicare IN triglycerides strips 25pcs
3830271 – Multicare IN triglycerides strips 5pcs
3830280 – Multicare IN glucose strips 50pcs
3830230 – Multicare IN glucose strips 25pcs
3830300 – Multicare IN control solution glucose
3830302 – Multicare IN control solution cholesterol
3830303 – Multicare IN control solution triglycerides
3809160 – Multicare cholesterol strips 25pcs
3809161 – Multicare cholesterol strips 5pcs
3809170 – Multicare triglycerides strips 25pcs
3809171 – Multicare triglycerides strips 5pcs
3809201 – Multicare control solution cholesterol
3809202 – Multicare control solution glucose

Manufacturer name
Manufacturer address

Biochemical Systems International S.p.A.
Loc. Palazzo del Pero, 23
52100 – Arezzo – ITALY
DEKRA CERTIFICATION B.V.

Notified body
EC Certificate no. 2094844CE03 dated 13/07/2012.

We, the undersigned, hereby declare, under our sole responsibility, that the above mentioned products conform to the specified Directive and Standards.
All supporting documents are retained at the premises of the manufacturer.

Biochemical Systems International S.p.A.
Emilio Dellepiane
Legal representative

Arezzo, 26/03/2019

Biochemical Systems International S.p.A.
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