

EC CERTIFICATE

Number: 2094844CE02

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 Srl

Località Palazzo del Pero 23
52100 Arezzo
Italy

For the product category(ies)

IVD system for diagnosis of blood analytes for self-testing use (wet chemistry)

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 14 September 2009

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 2019
Issued for the first time: 14 September 2009
Reissued: 1 March 2016

DEKRA Certification B.V.



drs. G.J. Zoetbrood
Managing Director



ing. A.A.M. Laan
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: 2094844CE02

1/1

CE MARKING OF CONFORMITY IN VITRO DIAGNOSTIC MEDICAL DEVICES

IVD system for diagnosis of blood analytes for self-testing use (wet chemistry)

Issued to:

Biochemical Systems International Srl
Località Palazzo del Pero 23
52100 Arezzo
Italy

This certificate covers the following product(s):

(Annex II List B)

CLINIC ANALYZER

Screen Master Plus, including a centrifuge and reagents for testing of cholesterol, glucose, triglycerides, lactic acid, hematocrit, heamaglobin, erythrocytes.

CLIN CHECK / Clin Check Alpha / Clin Check Plus

Evolution 2000 / Evolution 3000 / EMODOC, including reagents for testing of cholesterol, glucose, triglycerides, lactic acid, hematocrit, heamaglobin, erythrocytes.

Farnascreen, including a centrifuge and reagents for hematocrit, heamaglobin, erythrocytes, lactic acid, cholesterol, HDL cholesterol, glucose, triglycerides, ureic acid, free radicals, glycated heamaglobin, urine test strips, and rapid tests for PSA, ferritin, hCG, LH and microalbumin.

Initial date: 14 September 2009

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
Certification Manager

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