

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:

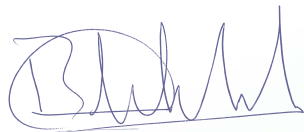
Certification Notice 2094844CN, initially dated 15 February 2007
Addendum, initially dated 13 July 2012

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

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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

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

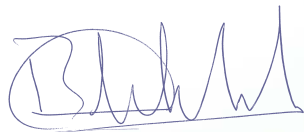
This certificate covers the following product(s):

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

Initial date: 13 July 2012

Revision date: 11 March 2022

DEKRA Certification B.V.

A blue ink signature of B.T.M. Holtus, the Managing Director of DEKRA Certification B.V.

B.T.M. Holtus
Managing Director

A blue ink signature of J.A. van Vugt, the Certification Manager of DEKRA Certification B.V.

J.A. van Vugt
Certification Manager

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Arnhem, 23 May 2025

Subject: Notified Body Confirmation Letter

To whom it may concern,

Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation EU 2024/1860 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices

This letter confirms that, DEKRA Certification B.V., a Notified Body (NB) designated against Regulation (EU) 2017/746 (IVDR) and identified by the number 0344 on NANDO, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of IVDR and has signed a written agreement (dated 12 May 2025) in accordance with Section 4.3, second subparagraph of Annex VII of IVDR with the following manufacturer:

Biochemical Systems International S.p.A.
Località Palazzo del Pero 23
52100 Arezzo
ITALY
SRN ID.: IT-MF-000028905

The devices covered by the formal application and the written agreement mentioned above are identified in the Tables below. Table 1 identifies the devices for which an IVDR application has been received, written agreement concluded and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the Directive 98/79/EC. Table 2 identifies the devices for which an IVDR application has been received and a written agreement concluded, but the NB has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the Directive 98/79/EC.

In the case of devices covered by certificates issued under Directive 98/79/EC (IVDD) that expired after 26 May 2022 and before 09 July 2024, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under IVDR by the date of IVDD certificate expiry; or provided evidence that a competent authority of a Member State had granted a derogation or exemption from the applicable conformity assessment procedure in accordance with Article 54 of IVDR or Article 92 of the IVDR respectively, by the 09 July 2024 for the relevant devices.

The transition timelines that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 110.3c of IVDR (as amended by (EU) 2024/1860), are shown below:

- 31 December 2027 for devices covered by an IVDD certificate regardless of their risk class under the IVDR
- For devices not requiring the involvement of a notified body under the IVDD, but requiring it under the IVDR and for which a declaration of conformity was drawn up prior to 26 May 2022 in accordance with Directive 98/79/EC, the following dates apply:
 - 31 December 2027, for class D devices;
 - 31 December 2028, for class C devices;
 - 31 December 2029, for class B devices and for class A devices placed on the market in sterile condition

On behalf of the Notified Body,



Daphne Hessels
Project Manager

Table 1: Devices covered by this letter and for which the NB is also responsible for appropriate surveillance of the corresponding devices under Directive 98/79/EC:

| Device name or Basic UDI-DI (under IVDR application) | IVDR Device classification (as proposed by the manufacturer and verified at the pre-application stage) | If the IVDR device is a substitute device, identification of the corresponding IVDD device | IVDD/ Certificate Reference(s) of the devices under IVDR application, and the NB Identification |
|--|--|--|---|
| multiCare-in® | Class C | N/A | 2094844CE03 NB: 0344 |
| Aria | Class C | N/A | 2094844CE03 NB: 0344 |
| OGCare | Class C | N/A | 2094844CE03 NB: 0344 |

Table 2: Devices covered by this letter and for which the NB is NOT responsible for appropriate surveillance of the corresponding devices under Directive 98/79/EC:

| Device name or Basic UDI-DI (under IVDR application) | IVDR Device classification (as proposed by the manufacturer and verified at the pre-application stage) | If the IVDR device is a substitute device, identification of the corresponding IVDD device | IVDD Certificate Reference(s) of the devices under IVDR application, and the NB Identification |
|--|--|--|--|
| N/A | N/A | N/A | N/A |

Confirmation Letter Revision History

| Date | Certification Notice (No. + Ver.) | Action |
|------------|-----------------------------------|---------------|
| 2025-05-23 | 2094844CN22.1 | Initial issue |