

EC Certificate

Full Quality Assurance System
Directive 98/79/EC on In Vitro Diagnostic Medical Devices,
Annex IV excluding (4, 6)

Registration No.: HL 2110160-1

Manufacturer: Bionime Corporation
No. 100, Sec. 2, Daqing St.,
South Dist., Taichung City 40242
Taiwan

Products:

- Blood Glucose Monitoring System (including blood glucose meter, blood glucose test strip, control solution, and mobile application/APP)
- Blood Glucose and Ketone Monitoring System (including blood glucose and ketone meter, blood glucose test strip, ketone test strip, control solution, ketone control solution)

The Notified Body hereby declares that the requirements of Annex IV, excluding sections 4 and 6 of the directive 98/79/EC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex IV, section 5 of the aforementioned directive. For placing on the market of List A devices covered by this certificate an EC design-examination certificate according to Annex IV, section 4 and a verification of manufactured products according to section 6 is required.

Report No.: 238541815-030

Effective date: 2022-05-24

Expiry date: 2025-05-26

Issue date: 2022-05-24



Fuxin Sheng
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 98/79/EC concerning in vitro diagnostic medical devices with the identification number 0197.

EC Certificate

Full Quality Assurance System
Directive 98/79/EC on In Vitro Diagnostic Medical Devices,
Annex IV excluding (4, 6)

Registration No.: HL 2110160-1

Manufacturer: Bionime Corporation
No. 100, Sec. 2, Daqing St.,
South Dist., Taichung City 40242
Taiwan

The scope of certification includes the following manufacturing sites:

No.	Location	Product groups manufactured
/01	Bionime Corporation Daqing Factory No. 100, Sec. 2, Daqing St., South Dist., Taichung City 40242 Taiwan	- Blood Glucose Monitoring System (including blood glucose meter, blood glucose test strip, control solution, and mobile application/APP) - Blood Glucose and Ketone Monitoring System (including blood glucose and ketone meter, blood glucose test strip, ketone test strip, control solution, ketone control solution)

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TÜV Rheinland LGA Products GmbH • 51105 Köln

Bionime Corporation
No. 100, Sec. 2, Daqing St., South Dist.
Taichung City
40242
Taiwan

Contact

Tel. +886 2 2172 7000
Mail: med-mailin@tw.tuv.com
Date July 04, 2025

Notified Body Confirmation Letter

Reference. : Bioni_PDQ0_2025-05-21, order no. 48272245

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 in vitro diagnostic medical devices.

This letter confirms that **TÜV Rheinland LGA Products GmbH**, a Notified Body (NB) designated against Regulation (EU) 2017/746 (IVDR) and identified by the number **0197** 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 in accordance with Section 4.3, second subparagraph of Annex VII of IVDR with the following manufacturer:

Bionime Corporation
No. 100, Sec. 2, Daqing St., South Dist.,
Taichung City
40242
Taiwan
SRN Number (if available): TW-MF-000008450

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 under the applicable 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 applicable Directive 98/79/EC.

In the case of devices covered by certificates issued under Directive 98/79/EC (IVDD) that expired after May 26, 2022 and before July 9, 2024, without having been withdrawn, this letter also confirms that the manufacturer either 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 July 9, 2024 for the relevant devices.

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LGA Products GmbH

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Nuremberg HRB 26013
VAT No.: DE 811835490

Chairman of the
Supervisory Board

Dr.-Ing. Michael Fübi

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

Ning Chang

Ning N. C. Chang
Certification body

Table 1: Devices covered by this letter and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable 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
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RIGHTTEST Blood Glucose Monitoring System GM700S (GM780) Basic UDI-DI: 471094933BGM0000495	C, self-testing C, near-patient testing	Bionime Rightest Blood Glucose Monitoring System GM700S	Certificate no.: HL 2110160-1 NB#0197
RIGHTTEST Blood Glucose Meter GM700S (GM780) Basic UDI-DI: 471094933BGM0000495	C, self-testing C, near-patient testing	Bionime Rightest Blood Glucose Meter GM700S	Certificate no.: HL 2110160-1 NB#0197
RIGHTTEST Blood Glucose Test Strip GS700 Basic UDI-DI: 471094933BGM0000495	C, self-testing C, near-patient testing	Bionime Rightest Blood Glucose Test Strip GS700	Certificate no.: HL 2110160-1 NB#0197
RIGHTTEST Control Solution GC700 Basic UDI-DI: 471094933BGM0000495	C, self-testing C, near-patient testing	Bionime Rightest Control Solution GC700	Certificate no.: HL 2110160-1 NB#0197

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REAL CARE Blood Glucose Monitoring System RC100 (GM555) Basic UDI-DI: 471094933BGM000108Y	C, self-testing C, near-patient testing	N/A	Certificate no.: HL 2110160-1 NB#0197
REAL CARE Blood Glucose Meter RC100 (GM555) Basic UDI-DI: 471094933BGM000108Y	C, self-testing C, near-patient testing	N/A	Certificate no.: HL 2110160-1 NB#0197
REAL CARE Blood Glucose Test Strip RC100 (GS250) Basic UDI-DI: 471094933BGM000108Y	C, self-testing C, near-patient testing	N/A	Certificate no.: HL 2110160-1 NB#0197
REAL CARE Control Solution RC100 (GC550) Basic UDI-DI: 471094933BGM000108Y	C, self-testing C, near-patient testing	N/A	Certificate no.: HL 2110160-1 NB#0197

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Table 2: Devices covered by this letter and for which the NB is NOT responsible for appropriate surveillance of the corresponding devices under the applicable 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	NB internal reference traceable to each version of the letter	Action
2025-07-04	#48272245	Initial issue