

TÜV Rheinland LGA Products GmbH • 51105 Köln

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

Contact

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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issued under Directive 98/79/EC (IVDD) that expired after May 26, 2022 and before July 9, 2024, without having been withdrawn, this letter also confirms that the manufacturer either signed the written agreement under IVDR by the date of IVDD certificate expiry; or provided evidence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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Board of Management

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Thomas Weigand, Spokesman

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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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Additional Trade Name : mylife Pura Blood Glucose Monitoring System (GM550) Basic UDI-DI: 471094933BGM000018X	C, self-testing C, near-patient testing	N/A	Certificate no.: HL 2110160-1 NB#0197
Additional Trade Name : mylife Pura Blood Glucose Meter (GM550) Basic UDI-DI: 471094933BGM000018X	C, self-testing C, near-patient testing	N/A	Certificate no.: HL 2110160-1 NB#0197
Additional Trade Name : mylife Pura Blood Glucose Test Strip (GS550) Basic UDI-DI: 471094933BGM000018X	C, self-testing C, near-patient testing	N/A	Certificate no.: HL 2110160-1 NB#0197
Additional Trade Name : mylife Control control solution (GC550) Basic UDI-DI: 471094933BGM000018X	C, self-testing C, near-patient testing	N/A	Certificate no.: HL 2110160-1 NB#0197
Additional Trade Name : mylife Pura X Blood Glucose Monitoring System (GM550) Basic UDI-DI: 471094933BGM000018X	C, self-testing C, near-patient testing	Additional Trade Name : mylife Pura Blood Glucose Monitoring System	Certificate no.: HL 2110160-1 NB#0197
Additional Trade Name : mylife Pura X Blood Glucose Meter (GM550) Basic UDI-DI: 471094933BGM000018X	C, self-testing C, near-patient testing	N/A	Certificate no.: HL 2110160-1 NB#0197

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Additional Trade Name : mylife Unio Blood Glucose Monitoring System (GM720) Basic UDI-DI: 471094933BGM0000699	C, self-testing C, near-patient testing	N/A	Certificate no.: HL 2110160-1 NB#0197
Additional Trade Name : mylife Unio Blood Glucose Meter (GM720) Basic UDI-DI: 471094933BGM0000699	C, self-testing C, near-patient testing	N/A	Certificate no.: HL 2110160-1 NB#0197
Additional Trade Name : mylife Unio Blood Glucose Test Strip (GS700, GS720) Basic UDI-DI: 471094933BGM0000699	C, self-testing C, near-patient testing	N/A	Certificate no.: HL 2110160-1 NB#0197
Additional Trade Name : mylife ControlIGDH control solution (GC700) Basic UDI-DI: 471094933BGM0000699	C, self-testing C, near-patient testing	N/A	Certificate no.: HL 2110160-1 NB#0197

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mylife Unio Neva Blood Glucose Monitoring System (GM722) Basic UDI-DI: 471094933BGM000079B	C, self-testing C, near-patient testing	Bionime Rightest Control Solution GC550	Certificate no.: HL 2110160-1 NB#0197
mylife Unio Neva Blood Glucose Meter (GM722)	C, self-testing C, near-patient testing	N/A	Certificate no.: HL 2110160-1

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Basic UDI-DI: 471094933BGM000079B			NB#0197
mylife Unio Blood Glucose Test Strip (GS720)	C, self-testing C, near-patient testing	N/A	Certificate no.: HL 2110160-1 NB#0197
Basic UDI-DI: 471094933BGM000079B			
mylife ControlGDH control solution (GC700)	C, self-testing C, near-patient testing	N/A	Certificate no.: HL 2110160-1 NB#0197
Basic UDI-DI: 471094933BGM000079B			

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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