

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



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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.

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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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