TÜVRheinland®

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

TÜV Rheinland LGA Products GmbH Zertifizierstelle

Fuxiu 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.

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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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BIONIME

Declaration Letter

To whom it may concern

We, Bionime Corporation, hereby declare that products under RIGHTEST: Blood Glucose Meter, Blood Glucose Test Strip, Glucose Control Solution and Blood Glucose Monitoring System, will be comply to Regulation (EU) 2024/1860 which The validity of certificates issued under Directive 98/79/EC on in vitro diagnostic medical devices refer to Regulation (EU) 2024/1860 Article 2, (3)(c), 3a and 3b.

- The validity of certificates issued under Directive 98/79/EC on in vitro diagnostic medical devices refer to Regulation (EU) 2024/1860 Article 2, (3)(c), 3a and 3b.
- The compliance of the devices and us as their manufacturer with the conditions for the continued placing on the market and putting into service refer to Regulation (EU) 2024/1860 Article 2, (3)(c), 3c.
- There has been no significant change in the design and intended purpose of the devices. The devices do not present an unacceptable risk to the health or safety of patients, users, or other persons, or to other aspects of the protection of public health.

In relation to Regulation (EU) 2023/607 amending Regulations (EU) 2017/745 as regards the transitional provisions for certain medical devices, the product under RIGHTEST: Lancing Device GD500 will comply with

- The conformity assessment procedures of Class I medical device refer to Regulation (EU) 2017/745 Article 52, 7.
- The compliance of the devices and us as their manufacturer with the conditions for the continued placing on the market and putting into service refer to Regulation (EU) 2017/745 Annex I for Class I medical device.
- There has been no significant change in the design and intended purpose of the devices. The devices do not present an unacceptable risk to the health or safety of patients, users, or other persons, or to other aspects of the protection of public health.

Bionime Corporation

華廣生技股份有限公司 BIONIME CORPORATION

2024. Aug. 05

Jessie Chen / Regulatory Persons

華廣生技股份有限公司 | BIONIME CORPORATION

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