

Certificate

Quality Management System EN ISO 13485:2016

Registration No.: SX 2110160-1

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

Scope: Design and Development, Manufacture, Distribution, Installation and Service of in vitro diagnostic medical device used in the management of blood glucose including meters, test strips, control solution and mobile application/App for home use, near-patient testing/point-of-care.
Design and Development, Manufacture, Distribution, Installation and Service of blood glucose, cholesterol, blood uric acid, ketone including meters, test strips and control solution for home use, near-patient testing/point-of-care.
Design and Development, Manufacture, Distribution of medical device used in the management of continuous glucose monitoring systems (CGMS) including Inserter, Transmitter, Receiver, mobile application/APP and Charger for home use and professional use.

The Certification Body of TÜV Rheinland LGA Products GmbH certifies that the organization has established and applies a quality management system for medical devices.
Proof has been furnished that the requirements specified in the abovementioned standard are fulfilled. The quality management system is subject to yearly surveillance.

Report No.: 48222065-040

Effective date: 2024-06-14

Expiry date: 2026-10-17

Issue date: 2024-06-14

Replaces certificate SX 2110160-1 issued 2023-10-13

This certificate can be validated on <https://www.certipedia.com>


Yunong Chen
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

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The scope of certification also covers the following sites:

No.	Facility	Scope
/01	c/o Bionime Corporation Daqing Factory No. 100, Sec. 2, Daqing St., South Dist., Taichung City 40242 Taiwan	Design and Development, Manufacture, Distribution, Installation and Service of in vitro diagnostic medical device used in the management of blood glucose including meters, test strips, control solution and mobile application/App for home use, near-patient testing/point-of-care. Design and Development, Manufacture, Distribution, Installation and Service of blood glucose, cholesterol, blood uric acid, ketone including meters, test strips and control solution for home use, near-patient testing/point-of-care. Design and Development, Manufacture, Distribution of medical device used in the management of continuous glucose monitoring systems (CGMS) including Inserter, Transmitter, Receiver, mobile application/APP and Charger for home use and professional use.

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