

Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

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

has established and applies a quality management system for medical devices
for the following scope:

**Design and Development, Manufacture, Distribution,
Installation and Service of Medical Devices**
(see attachment for products and additional site included)

Proof has been furnished that the requirements specified in

EN ISO 13485:2016

are fulfilled. The quality management system is subject to yearly surveillance.

Effective Date: 2017-10-18
Certificate Registration No.: SX 60121858 0001
An audit was performed. Report No.: 50082053 001
This Certificate is valid until: 2020-10-17

Certification Body



Date 2017-09-30



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TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

**Attachment to
Certificate**

Registration No.: SX 60121858 0001
Report No.: 50082053 001

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

Scope:

Products:
In-vitro diagnostic medical device used in the management of blood glucose, cholesterol, blood uric acid including meters, test strips, and control solution for home use, near patient/point of care

Site included:
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, cholesterol, blood uric acid including meters, test strips, and control solution for home use, near patient/point of care

Certification Body



Date: 2017-09-30

