



TÜVRheinland®

EC Certificate

Directive 98/79/EC Annex IV, excluding Sections 4 and 6
Full Quality Assurance System
In Vitro Diagnostic Medical Devices

Registration No.: HL 60121856 0001

Report No.: 50082053 001

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

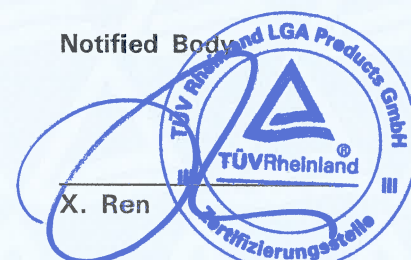
Products: Medical Products
(see attachment for products and additional site included)
Replaces Certificate, Registration No.: HL 60113735 0001

Expiry Date: 2022-10-17

The Notified Body hereby declares that the requirements of Annex IV, excluding section 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.

Effective Date: 2017-10-18

Date: 2017-09-30



TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg

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.

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

**Attachment to
Certificate**

Registration No.: HL 60121856 0001
Report No.: 50082053 001

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 and Control Solution)
- Cholesterol Monitoring System (including Cholesterol Meter, Cholesterol Test Strip and Cholesterol Control Solution)
- Blood Uric Acid Monitoring System (including Blood Uric Acid Meter, Blood Uric Acid Test Strip and Blood Uric Acid Control Solution)

Site included:

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

Date: 2017-09-30

