CE

0197

EC DECLARATION OF CONFORMITY

BIONIME Corporation declares that the product below meet the provisions of Directive 98/79/EC which apply to them.

Blood Glucose Monitoring System .
(Product Name)

UMDNS Number: 21 07 10 01, 11 50 02 05, 11 70 01 01 .
(Product Code, For In-Vitro-Diagnostics the EDMS Classification shall be used if possible.)

Rightest GM300 Non-sterile Product.
(Model Designation) (Product Type)

According to the Annex II of the Directive 98/79/EC, the device is categorized into List B, Self-testing device.

Compliance of the designated product with the Directive 98/79/EC has been assessed and certified by the Notified Body

TÜV Rheinland LGA Products GmbH
Tillystraße 2 90431 Nürnberg, Country : Germany
Certificate No.: HL 60121856 0001
Issue date: 2017-09-30 Expiry date: 2022-10-17

following the procedure relating to the EC Declaration of Conformity set out in Annex IV excluding section 4 and 6 of Directive 98/79/EC.

This Declaration of conformity is valid in connection with the release document for the respective serial of produced devices. The Declaration of Conformity covers all medical devices as specified in the product list belonging to this declaration and is only valid in connection with a batch specific Certificate of compliance for all products concerned bearing the CE mark.

European Authorized Representative:

BIONIME GmbH
(EU Rep's Name)

Tramstrasse 16, 9442 Berneck / Switzerland
(EU Rep's Address)

Person responsible for making this declaration:

BIONIME Corporation
(Manufacturer Name)

NO. 100, SEC. 2, DAQING ST., SOUTH DIST., 40242 TAICHUNG CITY, TAIWAN
(Place , Manufacturer Address)

Chairman Roy Hung Jan. 12, 2018
(Position／Title) (Legal Signature) (Date)