



EC Declaration of Conformity

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Manufacturer:

whose single Authorized Representative:

ANDON HEALTH CO., LTD.
No.3 Jinping Street, Ya An Road,Nankai
District, Tianjin, China

iHealth Labs Europe SAS
36 rue de Ponthieu, 75008, Paris, France

We, the manufacturer, herewith declare that the products

Blood Glucose Monitor

EDMS-Code: 21.07.10.01; GMDN-Code:

Model: AG-607, BG1, BG5, BG5S

The App used on mobile device for BG1, BG5 and BG5S is

App market name: iHealth Gluco-smart

APP model name: iGluco

meet the provisions of Directive IVDD 98/79/EC Annex IV which apply to them.

The medical device has been assigned to List B according to IVDD 98/79/EC Annex II. It bears the mark

CE 0197

The product concerned has been manufactured under a quality management system according to IVDD 98/79/EC Annex IV.

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

TÜV Rheinland LGA Products GmbH
Tillystraße 2, 90431, Nürnberg, Germany

Certificate No.: HL 60141764 0001

Issue date: 2019-08-08

Expiry date: 2024-05-27

Following the procedure relating to the EC Declaration of Conformity set out in IVDD 98/79/EC Annex IV.

This Declaration of conformity is valid in connection with the release document for the respective batch of produced devices.

The above mentioned declaration of conformity is exclusively under the responsibility of

ANDON HEALTH CO., LTD.
No.3 JinPing Street, Ya An Road,Nankai District, Tianjin, China

Tianjin WangYang Management Representative
Place name function

Wang Yang 2019/9/10
Legally binding signature, date