EC Declaration of Conformity

Manufacturer:

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

whose single Authorized Representative:

iHealth Labs Europe

3 rue Tronchet, 75008, Paris, France

We, the manufacturer, herewith declare that the products

Blood Glucose Monitor

EDMS-Code: 21.07.10.01; GMDN-Code:
Model:AG-605，AG-606，AG-695，AG-696，AG-632L（BG5），GMM 0002，AG-633（BG1），AG-680，AG-607

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 60107769 0001
Issue date: 15.04.2016
Expiry date: 05.11.2019

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 2017-1-20
Place, date

Helen Xie. MR
Legally binding signature, Function