

## EC Declaration of Conformity

Manufacturer:

whose single Authorized Representative:

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

**iHealthLabs Europe SARL**  
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-605, AG-606, AG-695, AG-696, AG-607, AG-608N1  
BG5, GMM0002, BG1, BG5S**

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.: HL60107769 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 / 2018.5.11  
Place, date

Helene Vee / MR  
Legally binding signature, Function