



EC Declaration of Conformity

## EC Declaration of Conformity

Manufacturer:

whose single Authorized Representative:

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

**iHealth Labs Europe**  
3 rue Tronchet, 75008, Paris, France

We, the manufacturer, herewith declare that the products

### Blood Glucose Test Strip

**EDMS-Code: 11.70.01.01; GMDN-Code:**

**Model: EGS-2000, EGS-2003**

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 IV. 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 2017-12-20  
Place, date

Helen Nie. MR.  
Legally binding signature, Function