



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, 300190, China

IHealth Labs Europe SAS

36 rue de Ponthieu, 75008, Paris, France

We, the manufacturer, herewith declare that the products

Blood Glucose Meter

EDMA-Code: 21.07.10.01; GMDN-Code: 62537

Model: BG1S, BG5S, BG5, BG1, AG-608N1

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 2095583-1

Issue date: 2022-05-21

Expiry date: 2025-05-26

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 WangYanhong Regulatory Affairs Wang Yanhong 2022-12-11
Place name function Legally binding signature, date

ANDON HEALTH CO., LTD

CE-BG-03



扫描全能王 创建



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, 300190, China

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

We, the manufacturer, herewith declare that the products

Blood Glucose Test Strip

EDMA-Code: 11.70.01.01; GMDN-Code: 17419

Model: EGS-2003, EGS-2043, EGS-2000

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 2095583-1
Issue date: 2022-05-21
Expiry date: 2025-05-26

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 WangYanhong Regulatory Affairs Wang Yanhong 2022-12-11
Place name function Legally binding signature, date

ANDON HEALTH CO., LTD

CE-strip-03



扫描全能王 创建



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, 300190, China

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

We, the manufacturer, herewith declare that the products

Control Solution

EDMA-Code: 11.50.02.05

Model: CS-BG, Level I, Level II, Level III

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 2095583-1
Issue date: 2022-05-21
Expiry date: 2025-05-26

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 WangYanhong Regulatory Affairs Wang Yanhong 2022-12-11
Place name function Legally binding signature, date

ANDON HEALTH CO., LTD

CE-control-03



扫描全能王 创建