



EU Declaration of Conformity

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Manufacturer:
Representative:

whose single Authorized

Andon Health Co., Ltd.
(SRN: CN-MF-000001799)
No. 3 Jinping Street, YaAn Road, Nankai
District, Tianjin, 300190 China

iHealthLabs Europe SAS
(SRN: FR-AR-000000340)
36 rue de Ponthieu, 75008, Paris, France

We, the manufacturer, herewith declare that the products

Product name	Model name
Blood Pressure Monitors	BP5S, KN-550BT, BP3L

Basic UDI-DI: 69302518BPMI02HJ

Intended use:

Fully Automatic Electronic Blood Pressure Monitor is for use by medical professionals or at home and is a non-invasive blood pressure measurement system intended to measure the diastolic and systolic blood pressures and pulse rate of an adult individual by using a non-invasive technique in which an inflatable cuff is wrapped around the upper arm.

meet the provisions of Regulation (EU) 2017/745 which apply to them.

The medical device has been assigned to class IIa according to Annex VIII of the Regulation (EU) 2017/745. It bears the mark



The product concerned has been designed and manufactured under a quality management system and technical documentation according to Annex IX of Regulation (EU) 2017/745.

Compliance of the designated product with the Regulation (EU) 2017/745 has been assessed and certified by the Notified Body

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

Certificate No.: HZ 2095583-1

Issue date: 2024-10-10

Expiry date: 2029-10-09

Following the procedure relating to the EU Declaration of Conformity set out in Annex IV of Regulation 2017/745.

Compliance of the designated product with the Directive (EU) 2015/863, an amendment of the RoHS Directive 2011/65/EU, Article 4(1) has been assessed and certified.

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, YaAn Road, Nankai District, Tianjin, China

Tianjin WangYang Management Representative
Place name function

Legally binding signature, date