



EU Declaration of Conformity

## EU Declaration of Conformity

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      |
|----------------|-----------------|
| Pulse Oximeter | PO3M, PO6, PO6L |

**Basic UDI-DI:** 69302518PO0010CY

**Intended use:**

The Fingertip Pulse Oximeter is a non-invasive device intended for spot-checking of functional oxygen saturation of arterial hemoglobin (SpO<sub>2</sub>) and pulse rate. The portable fingertip device is indicated for adult patients in home and hospital environments (including clinical use in internist/surgery, anesthesia, intensive care, etc).

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

Wang Yang 2024.10.28  
Legally binding signature, date