

EC Declaration of Conformity

Manufacturer:

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

whose single Authorized Representative:

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

We, the manufacturer, herewith declare that the products

Pulse Oximeter

UMDNS-Code: 17-148;

Model: PO6, PO6L

meet the provisions of Directive 93/42/EEC which apply to them.

The medical device has been assigned to class IIa according to Annex IX of the Directive 93/42/EEC. It bears the mark

CE 0197

The product concerned has been designed and manufactured under a quality management system according to Annex II of Directive 93/42/EEC.

Compliance of the designated product with the Directive 93/42/EEC has been assessed and certified by the Notified Body

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

Certificate No.: HD 60149938 0001

Issue date: 2020-06-29

Expiry date: 2024-05-26

Following the procedure relating to the EC Declaration of Conformity set out in Annex II of Directive 93/42/EEC.

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 WangYang Management Representative
Place name function

WangYang 2020-07-16
Legally binding signature, date

CE-PO3M-03



扫描全能王 创建