

EC Declaration of Conformity

Manufacturer:

whose single Authorized Representative:

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

iHealthLabs Europe SARL
3 rue Tronchet, 75008, Paris, France

We, the manufacturer, herewith declare that the products

Pulse Oximeter

UMDNS-Code: **17-148**;

Model: PO3M

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 assured via assessment of the quality management system by the Notified Body

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

Certificate No.: HD 60097963 0001

Issue date: 2014-11-25

Expiry date: 2019-11-05

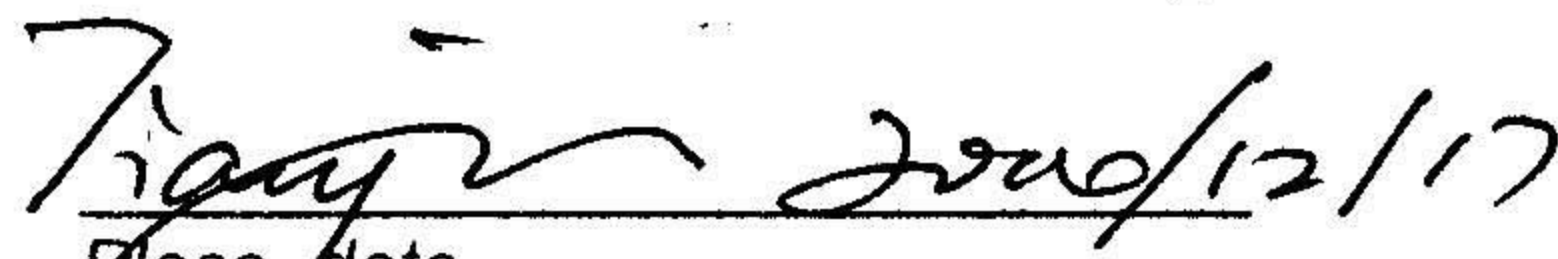
Following the procedure relating to the EC Declaration of Conformity set out in Annex II excluding section 4 of Directive 93/42/EEC.


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


Place, date


Legally binding signature, Function