

EC Declaration of Conformity

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Manufacturer:

whose single Authorized Representative:

Andon Health Co., Ltd.

iHealthLabs Europe SAS

No. 3 Jinping Street, YaAn Road, Nankai District, Tianjin, 300190 China

36 rue de Ponthieu, 75008, Paris, France

We, the manufacturer, herewith declare that the products

Electronic Sphygmomanometers

UMDNS-Code: 16-157;

Model: KD-595

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

(€ 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 60141761 0001 Issue date: 2019-08-08 Expiry date: 2024-05-27

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

Wand Yang 2019/9/20 Legally binding signature . date Tianjin WangYang Management Representative Place