EC Declaration of Conformity

Manufacturer:

ANDON HEALTH CO., LTD.
(SRN: CN-MF-000001799)
No.3 JinPing Street, Ya An Road,Nankai District, Tianjin, China

whose single Authorized Representative:

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

We, the manufacturer, herewith declare that the products

iHealth MyVitals App

Which is used together with the following devices:

Name of the product	Types
Electronic Sphygmomanometer	BP5S, BP7S, BP3L, BPM1, KN-550BT, KD-723
Pulse Oximeter	PO3M

With Basic UDI-DI: 00856362005951

And which is intended for use in home settings as an aid for people to review, analyze, and evaluate test results from iHealth devices of Electronic Sphygmomanometer (BP5S, BP7S, BP3L, BPM1, KN-550BT, KD-723) and Pulse Oximeter (PO3M)

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

The medical device has been assigned to class I according to Rule 11 in Annex VIII of the Regulation (EU) 2017/745. It bears the mark

CE

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.

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

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 (*Place*) WangYang (*name*) Management Representative (*function*) Wang Yang 2021-06-03 (*Legally binding signature, date*)