andon

EU Declaration of Conformity

Manufacturer:

Andon Health Co., Ltd.
(SRN: CN-MF-000001799)
No. 3 Jinping Street, YaAn Road, Nankai District, Tianjin, 300190 China

whose single Authorized Representative:

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

We, the manufacturer, herewith declare that the products

Blood pressure Cuff

Intended use:
Blood Pressure Cuff is intended to be wrapped on the upper arm and used with a non-invasive blood pressure monitor system to complete the measurement of blood parameters on adults.

Basic UDI-DI: 69302518CUF002ED

GIMA ITEM CODE : 32920	**SIZE : 42-48 CM**
GIMA ITEM CODE : 32922	**SIZE : 22-30 CM**
GIMA ITEM CODE : 32923	**SIZE : 30-42 CM**

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

The medical device has been assigned to class I according to 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 EU Declaration of Conformity set out 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, YaAn Road, Nankai District, Tianjin, China

安通卫安医疗电子股份有限公司
ANDON HEALTH CO.,LTD.

Tianjin	WangYang	Management Representative	Wang Yang 2021-07-26
Place	*name*	*function*	*Legally binding signature / date*