EU Certificate

Quality Management System
REGULATION (EU) 2017/745 on Medical Devices
Annex IX Chapter I, Section 2 and 3 and Chapter III

Registration No.:	HZ 2095583-1
Manufacturer:	Andon Health Co., Ltd. No. 3 Jinping Street YaAn Road, Nankai District 300190 Tianjin P.R. China
EUDAMED Single Registration No.:	CN-MF-000001799
Products:	Products of class IIa: Z120302 - VITAL SIGNS MONITORING INSTRUMENTS Z120628 - NEUROMUSCULAR STIMULATION EQUIPMENT V030101 - THERMOMETERS Z120306 - VITAL SIGNS TELEMETRY INSTRUMENTS (ECG, NIPB, EtCO2, SpO2, RESPIRATION,...)
Authorized representative(s):	iHealth Labs Europe SAS 36, Rue de Ponthieu 75008 Paris, France

Certificate history		
Revision:	Description:	Issue date:
0	Initial certification	2024-10-10

The Notified Body hereby declares that the requirements of Annex IX, Chapter I, Section 2 and 3 of the REGULATION (EU) 2017/745 have been met for the listed products. The above named manufacturer has established and applies a quality management system, which is subject to periodic surveillance, defined by Annex IX, Chapter I, Section 3 of the aforementioned regulation. The requirements of Annex IX, Chapter III are fulfilled.
If class III devices or class IIb implantable devices referred to in the second subparagraph of Article 52(4) are covered by this certificate an EU technical documentation assessment certificate according to Chapter II, Section 4.9 is required before placing them on the market.

Report No.:	244498120-200
Effective date:	2024-10-10
Expiry date:	2029-10-09
Issue date:	2024-10-10

Jason Pan
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This certificate can be validated on https://www.certipedia.com

TÜV Rheinland LGA Products GmbH is a Notified Body according to REGULATION (EU) 2017/745 concerning medical devices with the identification number 0197.

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