TÜVRheinland®

Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

Andon Health Co., Ltd.
No. 3 Jinping Street,
YaAn Road, Nankai District
Tianjin, 300190
P.R. China

has established and applies a quality management system for medical devices for the following scope:

Design and Development, Manufacture and Distribution of Medical Devices
(see attachment for products and additional site included)

Proof has been furnished that the requirements specified in

EN ISO 13485:2016

are fulfilled. The quality management system is subject to yearly surveillance.

Effective Date:	2020-06-29
Certificate Registration No.:	SX 60149940 0001
An audit was performed. Report No.:	15073607 023
This Certificate is valid until:	2020-10-20

Certification Body

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

TÜV Rheinland LGA Products GmbH
TÜVRheinland®
Zertifizierungsstelle

Date 2020-06-29

Dipl.-Ing. W. Hsu

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Doc. 1/1, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: SX 60149940 0001
Report No.: 15073607 023

Organization:
Andon Health Co., Ltd.
No. 3 Jinping Street,
YaAn Road, Nankai District
Tianjin, 300190
P.R. China

Scope:

Products:
Ambulatory Blood Pressure Monitors, Electronic Sphygmomanometers, Electrical Muscle Stimulators, TENs Devices, Digital Thermometers, Infrared Ear Thermometers, Foetal Dopplers, Handheld Massagers, Rhinitis Retrievers, Blood Viscosity Therapeutic Equipments, Phototherapy Devices, Hypertension Treatment Devices, AC/DC Adapters, Blood Glucose Meters, Blood Glucose Test Strips for Self-testing, Digital Pregnancy Tests, Digital Ovulation Tests, Digital Pregnancy and Digital Ovulation Tests, Pregnancy Test Strips, Ovulation Test Strips, Portable ECG Monitors, Lancets, Lancing Devices, Fingertip Pulse Oximeter, Control Solution for Blood-glucose Monitoring Systems for self-testing Infrared Forehead Thermometers
Site included:
Andon Medical Co., Ltd.
No.26 HangYu Road, Tianjin Airport Economic Area, Tianjin 300380, China
Manufacture of the a.m. products

Certification Body

DAkkS
Deutsche Akkreditierungsstelle
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