

Certificate


Quality Management System EN ISO 13485:2016

Registration No.	SX 2095583-1
Certificate Holder	Andon Health Co., Ltd. No. 3 Jinping Street YaAn Road, Nankai District 300190 Tianjin P.R. China
Scope	Design and development, Manufacture and Distribution of Medical Devices: Ambulatory Blood Pressure Monitors, Electronic Sphygmomanometers, Electrical Muscle Stimulators, Transcutaneous Electrical Nerve 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 used for Medical Devices, Portable ECG Monitors, Lancets, Lancing Devices, Fingertip Pulse Oximeter, Infrared Forehead Thermometers; Design and development, Manufacture and Distribution of in vitro diagnostic medical devices(reagents, controls, instruments) used in the monitoring of blood glucose and in the detection of the pregnancy testing, Fertility testing, Infectious Diseases including(home use, near patient/point of care) in vitro diagnostic devices

The Certification Body of TÜV Rheinland LGA Products GmbH certifies that the organization has established and applies a quality management system for medical devices.
Proof has been furnished that the requirements specified in the abovementioned standard are fulfilled. The quality management system is subject to yearly surveillance.

Report No.	244524096-200
Effective date	2023-10-21
Expiry date	2026-10-20
Issue date	2023-10-08
Replaces certificate SX 2095583-1 issued 2022-09-08	

This certificate can be validated on <https://www.certipedia.com>


Fuxiu Sheng
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

© TÜV, TÜV and TÜV are registered trademarks. Utilisation and application requires prior approval.

Certificate

Quality Management System EN ISO 13485:2016

Registration No. SX 2095583-1
Certificate Holder Andon Health Co., Ltd.
No. 3 Jinping Street
YaAn Road, Nankai District
300190 Tianjin
P.R. China

The scope of certification also covers the following sites:

No.	Facility	Scope
/01	c/o Andon Health Co., Ltd. No. 3 Jinping Street YaAn Road, Nankai District 300190 Tianjin P.R. China	Aspects related to Design and Development and Distribution
/02	c/o Andon Medical Co., Ltd. No.26 HangYu Road, Tianjin Airport Economic Area, 300380 Tianjin P.R. China	Aspects related to Manufacturing

Report No. 244524096-200
Effective date 2023-10-21
Expiry date 2026-10-20
Issue date 2023-10-08



Fuxiu Sheng
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

This certificate can be validated on <https://www.certipedia.com>