Certificate

Quality Management System
EN ISO 13485:2016 + AC:2018 + A11:2021
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 Relievers, 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, Insect Bite Healers, TENS/EMS Devices; 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

ANDON HEALTH CO.,LTD

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.:	326198358-200
Effective date:	2026-10-21
Expiry date:	2029-10-20
Issue date:	2026-10-08

Replaces certificate SX 2095583-1 issued 2026-05-25

Jason Pan

Jason Pan
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

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

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DAkkS Deutsche Akkreditierungsstelle D-ZM-14169-01-00

TÜVRheinland®
Precisely Right.

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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	Design and Development, 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 Relievers, 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, Insect Bite Healers, TENS/EMS Devices; Design and Development, 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
/02	c/o Andon Medical Co., Ltd. No.26 HangYu Road, Tianjin Airport Economic Area, 300380 Tianjin P.R. China	Manufacture 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 Relievers, 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, Insect Bite Healers, TENS/EMS Devices; Manufacture 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

ANDON HEALTH CO., LTD.

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