

Certificate

Quality Management System EN ISO 13485:2016

Registration No.: SX 2095583-1

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

Scope: Design/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/development, Manufacture and Distribution of Blood Glucose Monitoring Systems Consisting of Blood Glucose Meters, Blood Glucose Test Strips and Control Solutions, Digital Pregnancy Tests, Digital Ovulation Tests, Digital Pregnancy and Digital Ovulation Tests, Pregnancy Test Strips, Ovulation Test Strips for self-testing 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.: 15073607 025

Effective date: 2020-10-21

Expiry date: 2023-10-20

Issue date: 2020-09-24



Dipl.-Ing. W. Hsu
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

Certificate

**Quality Management System
EN ISO 13485:2016**

Registration No.: SX 2095583-1

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

The scope of certification also includes the following additional facilities:

No.	Facility	Scope
/01	Andon Medical Co., Ltd. No.26 HangYu Road, Tianjin Airport Economic Area, Tianjin 300380 China	<p>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 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.</p> <p>Manufacture of Blood Glucose Monitoring Systems Consisting of Blood Glucose Meters, Blood Glucose Test Strips and Control Solutions, Digital Pregnancy Tests, Digital Ovulation Tests, Digital Pregnancy and Digital Ovulation Tests, Pregnancy Test Strips, Ovulation Test Strips for self-testing in-vitro diagnostic devices</p>

Report No.: 15073607 025

Effective date: 2020-10-21

Expiry date: 2023-10-20

Issue date: 2020-09-24



Dipl.-Ing. W. Hsu
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany