Certificate

TÜVRheinland®

Quality Management System
EN ISO 13485:2016

Registration No.: SX 2156120-1

Organization: Wuxi Exanovo Medical Instrument
Co., Ltd.
No.42, Xixin Road, Xibei Town,
Wuxi City,
214194 Jiangsu
P.R. China

Scope: Manufacture and Distribution of Digital Thermometers, Sphygmomanometers and Stethoscopes

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.: 15074616 013

Effective date: 2020-11-25

Expiry date: 2023-10-21

Issue date: 2020-11-25

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

TÜV Rheinland LGA Products GmbH
Zertifizierungsstelle

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

Digitally signed by Granaci Boris
Date: 2022.12.07 16:21:39 EET
Reason: MoldSign Signature
Location: Moldova

Certificate

TÜVRheinland®

Quality Management System
EN ISO 13485:2016

Registration No.: SX 2021367-1

Organization: Wuxi Medical Instrument Factory
Co., Ltd.
No. 43, Xixin Road, Zhangjing, Xibei Town,
Wuxi City,
214194 Jiangsu
P.R. China

Scope: Manufacture and Distribution of Alcohol Pads, Mercury Free Clinical Thermometers, Sphygmomanometers, Stethoscopes

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.: 244310593-200
Effective date: 2021-05-13
Expiry date: 2024-03-18
Issue date: 2021-05-13

TÜV Rheinland LGA Products GmbH
TÜVRheinland®
Zertifizierungsstelle

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

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

Notified Body 1023
INSTITUTE FOR TESTING AND CERTIFICATION, Inc.,
třída Tomáše Bati 299, Louky, 763 02 Zlín, Czech Republic

EC Certificate - Production Quality Assurance
No. 19 0248 QS/NB

The quality system of manufacturer

Wuxi Medical Instrument Factory Co., Ltd.

No. 43 Xixin Road, Zhangjing, Xibei Town, Wuxi City, Jiangsu 214194 China

has been certified as meeting the requirements of

Directive 93/42/EEC

on medical devices, Annex V

for the following product category(ies):

Mercury free clinical thermometer

The Notified Body No. 1023 declares that the aforementioned manufacturer has implemented a quality assurance system for manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex V. The Notified Body has audited this system with limitation to those aspects of manufacture concerned with the conformity of the devices with metrological requirements. This part of quality assurance system conforms to the requirements of this Directive and is subjected to periodical surveillance.

Valid from: 2019-05-22
Valid until: 2024-05-21