

EC Certificate
Directive 93/42/EEC Annex V
Production Quality Assurance
Medical Devices

Registration No.: DD 60140917 0001

Report No.: 15074616 010

Manufacturer: Wuxi Exanovo Medical
Instrument Co., Ltd.
No. 42 Xixin Road,Zhangjing
Xibei Town
Wuxi City
214194 Jiangsu
China

Products: Digital Thermometers;

Aspects of manufacture concerned with conforming of products
with the metrological requirements: Sphygmomanometers

Replaces Approval, Registration No.: DD 60108265 0001

Expiry Date: 2024-05-27

The Notified Body hereby declares that the requirements of Annex V of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex V, section 4 of the aforementioned directive. For placing on the market of class IIb and class III devices covered by this certificate an EC type-examination certificate according to Annex III is required.

Effective Date: 2019-07-16

Date: 2019-07-16

Notified Body



TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC
concerning medical devices with the identification number 0197.

TÜV Rheinland LGA Products GmbH • 51105 Köln

Wuxi Exanovo Medical Instrument Co., Ltd.
C2-LianDong U Gu, Xibei Town, Xishan District,
Wuxi, 214194 Jiangsu, P.R. China

Contact

Tel. +49 911 655-5225
Mail: medical-products@de.tuv.com

Date January 17, 2023

Application for: QMS

Certificate No. : DD 60140917 0001
Requirement : Richtlinie 93/42/EWG
Confirmation letter ID : DOC_2023-01-17_DD 60140917 0001
Report no. : 244372107-200

Dear Madame or Sir,

Update of information to Certificate no. DD 60140917 0001, issued on 16. 07. 2019

The change notification received on 22.09.2021 related to the information stipulated on the above mentioned certificate was assessed and information confirmed.

We confirm that the change notification is not considered a significant change in design or intended purpose under Regulation (EU) 2017/745 on medical devices (MDR), Article 120(3).

With this document we would like to confirm the following updated information to the afore mentioned certificate

Revised Manufacturer address

Old Manufacturer address: No.42 Xixin Road, Zhangjing, Xibei Town, Wuxi City, 214194 Jiangsu, P.R. China

New Manufacturer address: C2-LianDong U Gu, Xibei Town, Xishan District, Wuxi, 214194 Jiangsu, P.R. China

Best regards,

Dipl.-Ing. W. Hsu
Certification body

TÜV Rheinland
LGA Products GmbH

Am Grauen Stein
51105 Köln
Germany

Headquarter

Tillystraße 2
90431 Nuremberg

Phone. +49 911 655 5225
Fax +49 911 655 5226
service@de.tuv.com
www.tuv.com/safetv

Board of Management

Dipl.-Ing.
Jörg Mähler, Spokesman

Dipl.-Kfm.
Dr. Jörg Schlösser

Nuremberg HRB 26013
VAT No.: DE 811835490

Chairman of the
Supervisory Board

Dipl.-Ing. Ralf Scheller

Certificate



Quality Management System
EN ISO 13485:2016

Registration No.: SX 2156120-1

Organization: Wuxi Exanovo Medical Instrument Co., Ltd.
C2-LianDong U Gu, Xibei Town, Xishan District,
Wuxi,
214194 Jiangsu
P.R. China

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

TÜVRheinland®

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.: 244372107-200
Effective date: 2022-12-16
Expiry date: 2023-10-21
Issue date: 2022-12-16



A handwritten signature in blue ink, appearing to read 'W. Hsu'.

Dipl.-Ing. W. Hsu

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

