Digitally signed by Neer Ghennadii
Date: 2023.03.01 13:43:19 EET
Reason: MoldSign Signature
Location: Moldova

TÜVRheinland®

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

Fuxiu Sheng

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.

Business Stream Products
Certification Department

TÜVRheinland®
LGA
Precisely Right.

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/safety