

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



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.

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

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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
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