

Certificate



**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



A handwritten signature in blue ink that reads "Jason Pan".
A circular blue seal for TÜV Rheinland LGA Products GmbH. The seal contains the text "TÜV Rheinland LGA Products GmbH", "TÜVRheinland", and "Zertifizierungsstelle".
Jason Pan
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

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

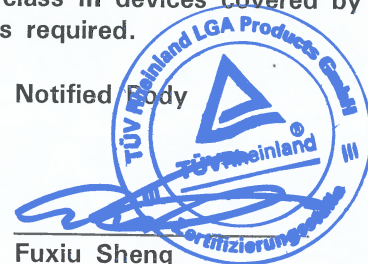
Expiry Date: 2024-05-27

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.

ANEROID SPHYGMOMANOMETER

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ANEROID

SPHYGMOMANOMETER



MC-20A

Zinc/Aluminum alloy gauge
Cotton standard cuff:54*14cm
Latex bulb and bladder:22*12cm
Accuracy:±3mmHg/Sub-division:2mmHg
Leather bag



MC-20B

Zinc/Aluminum alloy gauge
Nylon standard cuff with printing:54*14cm
Latex bulb and bladder:22*12cm
Accuracy:±3mmHg/Sub-division:2mmHg
Leather bag



MC-20C

Aluminum alloy gauge
Nylon standard cuff:54*14cm
PVC bulb and PVC bladder:22*12cm
Accuracy:±3mmHg/Sub-division:2mmHg
Leather bag



MC-20D

Zinc alloy gauge,heavy weight:140g
Prominent cuff with prominent velcro:54*14cm
Green latex bulb and bladder:22*12cm
Accuracy:±3mmHg/Sub-division:2mmHg
Leather bag