

Certificate



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



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

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





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
First Issued: 2019-05-22
Revision: -



Date: 2019-05-22

Mgr. Jiří Heš
Representative of the Notified Body No. 1023



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

Annex to EC Certificate No. 19 0248 QS/NB
issued for manufacturer:

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

Product(s):


Name: Mercury free clinical thermometer
Trade name(s): Mercury free clinical thermometer
Model(s): CR.W00
Class: Im
GMDN: 34343

Facility(ies):

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



Date: 2019-05-22
Revision: -


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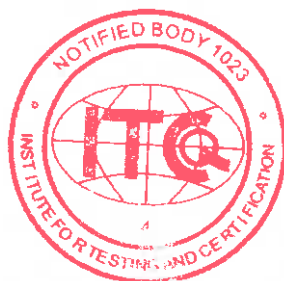
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Certificate History:

Revision	Date	Reference Number	Action
	2019-05-22	803602800	Certification



Date: 2019-05-22
Revision: -


Mgr. Jiří Heš
Representative of the Notified Body No. 1023