TÜVRheinland®

Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

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

has established and applies a quality management system for medical devices for the following scope:

Manufacture and Distribution of Alcohol Pads, Mercury Free Clinical Thermometers, Sphygmomanometers, Stethoscopes

Proof has been furnished that the requirements specified in

EN ISO 13485:2016

are fulfilled. The quality management system is subject to yearly surveillance.

Effective Date:	2018-05-09
Certificate Registration No.:	SX 60128374 0001
An audit was performed. Report No.:	15057479 010
This Certificate is valid until:	2021-03-18

Certification Body

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

TÜV Rheinland LGA Products GmbH
TÜVRheinland®
Zertifizierungsstelle

Date 2018-05-09

X. Ren

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
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Notified Body No. 1023
INSTITUTE FOR TESTING AND CERTIFICATION, Inc.
Zlin, Czech Republic – www.itczlin.cz

EC CERTIFICATE

No. 14 0077 QS/NB

issued in compliance with the Council Directive 93/42/EEC as amended, which is implemented by the Czech Government Order No. 336/2004 (Collection of Laws), certifies that the product – medical device of Class Im with a measuring function, model

Mercury free clinical thermometer, model CR. W00

manufactured by company

Wuxi Medical Instrument Factory
No. 86 East street, Zhangjing, Xibei Town, Wuxi City, Jiangsu, 214194 China

is manufactured under conditions fulfilling the quality system requirements of Annex V, Section 3.2., of the Directive 93/42/EEC.

The Notified Body No. 1023 has performed an audit of the above products manufacturing quality system, concerning aspects aimed to conformity of these products with the metrological requirements. The quality system has been assessed, approved and is subject to continuous surveillance according to Annex V, Sections 3.3, and 4, and Annex VII, Section 5, of the Directive 93/42/EEC. The detailed description of the system parts, requirements and measures applied by the manufacturer are presented in the Final Report No. 803602145/2014, which is enclosed to this Certificate.

This Certificate is issued under the following conditions:

1. *It applies only to the quality system maintained in the manufacture of the above referenced models of medical devices and it does not substitute the design or type-examination procedures, if requested.*
2. *The Certificate remains valid until the manufacturing conditions or the quality system are changed but until the **23rd February 2019** at the latest.*
3. *The Certificate validity is conditioned by positive results of surveillance audits.*
4. *After fulfilling the relevant EU legislation requirements, the manufacturer shall affix to each medical device, of the above referenced models, the CE marking followed by the number of the Notified Body according to this example:*

CE 1023

Issued in Zlín, on 24th February 2014

INSTITUTE FOR TESTING AND CERTIFICATION 1023 NOTIFIED BODY

RNDr. Radomír Čevelík
Representative of the Notified Body No. 1023