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: 2021-03-23
Valid until: 2024-05-21
First Issued: 2019-05-22
Revision: a

NOTIFIED BODY 1023 · INSTITUTE FOR TESTING AND CERTIFICATION · 6

Date: 2021-03-23

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):	AIESI; APTEO; EUROSIREL; EVOLU; FarmaMed; FLAEM; GIMA; ia; Lamotherm; Med+s; Sanitec; Tecnico; UNIFAMILY
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

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issued for manufacturer:

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No. 43 Xixin Road, Zhangjing, Xibei Town, Wuxi City,
Jiangsu 214194 China

Certificate History:

Revision	Date	Reference Number	Action
	2019-05-22	803602800	Certification
a	2021-03-23	803602897	Adding new brand names

NOTIFIED BODY 1023 · INSTITUTE FOR TESTING AND CERTIFICATION · 6

Date: 2021-03-23
Revision: a

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Business Stream Products
Certification Department

TÜVRheinland®
LGA
Precisely Right.

TÜV Rheinland LGA Products GmbH • 51105 Köln

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

Contact

Tel. +49 911 655-5225
Mail: medical-products@de.tuv.com

Date May 23, 2024

Notified Body Confirmation Letter
Reference. : Wuxim_PLA0_2024-03-12; order # 326019197

To whom it may concern,

Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation EU 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices.

This letter confirms that **TÜV Rheinland LGA Products GmbH**, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number **0197** on NANDO, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following manufacturer:

Wuxi Medical Instrument Factory Co., Ltd.
No. 43, Xixin Road, Zhangjing, Xibei Town,
Wuxi City, 214194 Jiangsu,
P.R. China
SRN Number (if available): CN-MF-000002277

The devices covered by the formal application and the written agreement mentioned above are identified in the tables below. Table 1 identifies the devices for which an MDR application has been received, written agreement concluded and for which the NB is also responsible for appropriate surveillance under the applicable Directive. Table 2 identifies the devices for which an MDR application has been received and a written agreement concluded, but the NB has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.

In the case of devices covered by certificates issued under Directive 90/385/EEC (AIMDD) or Directive 93/42/EEC (MDD) that expired after May 26, 2021 but before March 20, 2023 without having been withdrawn, this letter also confirms that the manufacturer either signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or provided evidence that a competent authority of a Member State had granted a derogation or exemption from the applicable conformity assessment procedure in accordance with Article 59(1) of MDR or Article 97(1) of the MDR respectively, by March 20, 2023 for the relevant devices.

TÜV Rheinland
LGA Products GmbH

Am Grauen Stein
51105 Köln
Germany

Headquarter

Tillystraße 2
90431 Nuremberg

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service@de.tuv.com
www.tuv.com/safety

The transition timelines that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120.3c of MDR (as amended by (EU) 2023/607), are shown below:

- May 26, 2026 for Class III custom-made implantable devices
- December 31, 2027 for Class III devices and Class IIb implantable devices excluding Well-established technologies (WET - sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors)
- December 31, 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function
- December 31, 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments)

On behalf of the Notified Body

Fuxiu Sheng
Certification body

Table 1: Devices covered by this letter and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Alcohol Pads **Model: D-020** **Basic UDI-DI:** **69486470ETHANOL6Y**	Class IIa	NA	Certificate No.: DD 60149032 0001 NB 0197
Mercury Free Clinical Thermometer **Model: CR.W00** **Basic UDI-DI:** **69486470THERMOMETERWP**	Class Im	NA	Certificate No.: 19 0248 QS/NB NB #1023

Table 2: Devices covered by this letter and for which the NB is <u>NOT</u> responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
NONE			

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
2024-05-23	Wuxim_CL607_2024-05-23	Initial issue