



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



Date: 2021-03-23


Mgr. Jiří Heš

Representative of the Notified Body No. 1023



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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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Certificate History:

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



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