



DECLARATION OF CONFORMITY

Manufacturer:

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

Whose Authorized Representative:

Name: Lotus NL B.V.
Address: Koningin Julianaplein 10,1e
Verd, 2595AA, The Hague, Netherlands.
SRN: NL-AR-000000121

We, the manufacturer, herewith declare that the products

Product Name	Intend use	Device Class	EMDN	Model	Basic UDI-DI
Mercury free clinical thermometer	Measure the temperature of human	Im, Rule 1	V03010104	CR.W00	69486470THERMOMETERWP

meet the provisions of the REGULATION (EU) 2017/745 which apply to them.

Conformity Assessment Route: Annex II and III according to REGULATION (EU) 2017/745.

Applicable Standards:

No.	Document Number	Document Title
1.	EN ISO13485:2016	Medical devices - Quality management systems - Requirements for regulatory purposes
2.	ISO 15223-1:2021/AMD 1:2025(en)	Medical devices - symbols to be used with medical device labels, labelling and information to be supplied - part 1: general requirements
3.	EN ISO 20417: 2021	Medical devices. Information to be supplied by the manufacturer
4.	ISO 14971:2019	Medical devices — Application of risk management to medical devices
5.	EN ISO 10933-1:2020	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
6.	ISO 719:2020	Glass hydrolytic resistance of glass at 98°C;method of test and classification
7.	EN12470-1:2000+A1:2009	Clinical thermometers - Part 1: Metallic liquid-in glass thermometers with maximum device
8.	IEC 62366-1:2015	Medical devices - Application of usability engineering to medical devices
9.	ASTM D 4169-16	Standard Practice for Performance Testing of Shipping Containers and Systems

Notified Body: TÜV Rheinland LGA Products GmbH

Tillystraße 2

90431 Nürnberg

Germany

EC certificate No.: HZ 2021367-1

Date of validity: 2030-08-28

Revision: 0

Signed:

Ding Yan ping

WUXI MEDICAL INSTRUMENT FACTORY CO., LTD
无锡市医用仪表厂有限公司

Date: 2025.09.01

Position held in the company: Vice General Manager

Place: Jiangsu, China