

# EU Certificate

## Quality Management System REGULATION (EU) 2017/745 on Medical Devices Annex IX Chapters I and III

Registration No.: HZ 2021367-1

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

EUDAMED Single  
Registration No.: CN-MF-000002277

Products: Products of class I, with measuring function:  
V030101 - THERMOMETERS  
-Mercury Free Clinical Thermometer  
The scope of certification is limited to the aspects relating to  
the conformity of the devices with the metrological  
requirements

Products of class IIa:  
D0701 - ETHANOL FOR THE DISINFECTION OF MEDICAL  
DEVICES  
-Alcohol Pads

The Notified Body hereby declares that the requirements of Annex IX, Chapter I of the REGULATION (EU) 2017/745 have been met for the listed products. The above named manufacturer has established and applies a quality management system, which is subject to periodic surveillance, defined by Annex IX, Chapter I, Section 3 of the aforementioned regulation. The requirements of Annex IX, Chapter III are fulfilled.

If class III devices or class IIb implantable devices referred to in the second subparagraph of Article 52(4) are covered by this certificate an EU technical documentation assessment certificate according to Chapter II, Section 4.9 is required before placing them on the market.

Report No.: 244532490-200

Effective date: 2025-08-29

Expiry date: 2030-08-28

Issue date: 2025-08-29



Herbert Zhong  
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This certificate can be validated on <https://www.certipedia.com>

TÜV Rheinland LGA Products GmbH is a Notified Body according to REGULATION (EU) 2017/745 concerning medical devices with the identification number 0197.

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Zentralstelle der Länder  
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BS-MDR-091



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Authorized representative(s): Lotus NL B.V.  
Koningin Julianaplein 10, 1e Verd, 2595AA, The Hague,  
Netherlands

| Certificate history |                       |             |
|---------------------|-----------------------|-------------|
| Revision:           | Description:          | Issue date: |
| 0                   | Initial certification | 2025-08-29  |

