

EC Declaration of Conformity

Manufacturer: **Wuxi Medical Instrument Factory Co., Ltd.**

Add: No. 43 Xixin Road, Zhangjing, Xibei town, Wuxi city, Jiangsu, 214194 China

European representative : **Lotus NL B.V.**

Add: Koningin Julianaplein 10, 1e Verd, 2595AA, The Hague, Netherlands.

Tel: 0031626669008

Product: Mercury free Clinical thermometer

Model: CR.W00

Classification: Im According to Rule 5, Annex IX of MDD 93/42/EEC amended by 2007/47/EC

Harmonized Standards:

EN ISO 15223-1:2021, EN 1041:2008+A1:2013, EN ISO 14971:2019,
EN 12470-1:2000+A1:2009, EN ISO 13485:2016, GB 1588:2001, ISO 719:1985.

Conformity Assessment Route: Annex V, MDD 93/42/EEC amended by 2007/47/EC

We herewith declare that the above mentioned products meet the provisions of the Council Directive 93/42/EEC amended by 2007/47/EC for medical devices. All supporting documentation is retained under the premises of the manufacturer.

Notified Body: INSTITUTE FOR TESTING AND CERTIFICATION, Inc.

Address: trida Tomase Bati 299, Louky, 763 02 Zlin Czech Republic

EC certificate No.: 19 0248 QS/NB

Date of issue: 2019-05-22

date of validity: 2028-12-31

Version: a

Ding Yanping / Vice GM

Signature:

Date: 2024-03-19

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