

EU DECLARATION OF CONFORMITY

According to Regulation (EU) 2017/745 on Medical Devices

Manufacturer: Wuxi Exanovo Medical Instrument Co., Ltd.
C2-Liandong U Gu, Xibei Town, Xishan District, Wuxi City,
214194Jiangsu, P.R. China

Trademark: 

SRN: CN-MF-000021396

European Representative: Lotus NL B.V.
Koningin Julianaplein 10, le Verd, 2595AA, The Hague, Netherlands.

SRN: NL-AR-000000121

Trade name: **Mercury free clinical thermometer**

Product Name: **Mercury free clinical thermometer**

Product Models/Catalogue number: MC-10

Basic UDI: 697069100MC003AL

Classification acc. to MDR Ax. VIII: Class Im, rule 1

Applied Standard & Common Specification: ISO 15223-1:2021, ISO 20417-2021, EN ISO 10993-1:2009/AC:2010, EN ISO 10993-5:2009, ISO 10993-10:2021, EN ISO 14971:2019/A11:2021, EN 62366-1:2015/A1:2020, EN ISO 13485:2016/A11:2021, EN 12470-1:2000+A1:2009

Conformity assessment procedure: **Annex XI Part A, MDR (2017/745)**

CE certificate No.: G21 115419 0002 Rev.00

Name and ID of the Notified Body: TÜV SÜD Product service GmbH
Ridlerstr 65, D-80339 München, Germany
Notified Body number :0123

We, the manufacturer, herewith declare under our sole responsibility that the above-mentioned products meet the provisions of the Regulation (EU) 2017/745 on Medical Devices (MDR). All supporting documentations are retained under the premises of the manufacturer.

HuangXiao ,
General Manager



Wuxi, Nov. 02. 2023

WUXI EXANOVO MEDICAL INSTRUMENT CO.,LTD.