

2024-02-06

To Whom It May Concern

TÜV Rheinland (Shanghai) Co., Ltd. confirms that the manufacturer GCMEDICA ENTERPRISE LTD. (WUXI) has lodged an application for conformity assessment based on MDR (EU) 2017/745 annex IX Chapter I, Section 2 and 3 and Chapter III.

MDD Certificate No: DD 60138811 0001, expiry date: 2024-02-07.
GCMEDICA ENTERPRISE LTD. (WUXI) signed the MDR certification contract on 2024-02-06, Quotation No. 245830336, The quotation is a formal contract between GCMEDICA ENTERPRISE LTD. (WUXI) and TÜV Rheinland (Shanghai) Co., Ltd.

The transition timelines according to (EU) 2023/607 are shown below:

- 26 May 2026 for Class III custom-made implantable devices
- 31 December 2027 for Class III devices and Class IIb implantable devices excluding Well-established technologies (WET - sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors)
- 31 December 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function
- 31 December 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments)

TÜV Rheinland (Shanghai) Co., Ltd. will continue to do MDD surveillance audit for the manufacturer GCMEDICA ENTERPRISE LTD. (WUXI).

Yours sincerely,
TÜV RHEINLAND (SHANGHAI) Co., Ltd.



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