TÜVRheinland®
Precisely Right.

2024-04-03

To Whom It May Concern

TÜV Rheinland (Shanghai) Co., Ltd. confirms that the manufacturer Changzhou Yimeng Medical Supplies Co., Ltd. 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 60147755 0001, expiry date: 2024-05-26.
Changzhou Yimeng Medical Supplies Co., Ltd. signed the MDR certification contract on 2023-11-30, Quotation No. 245823946, The quotation is a formal contract between Changzhou Yimeng Medical Supplies Co., Ltd. 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 Changzhou Yimeng Medical Supplies Co., Ltd.

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

Tony Chen

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