

2024-05-22

To Whom It May Concern

TÜV Rheinland (Shanghai) Co., Ltd. confirms that the manufacturer Jiangsu Caina Medical 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 2016352-1, expiry date: 2024-05-26.

Jiangsu Caina Medical Co., Ltd. signed the MDR certification contract on 2023-11-15, Quotation No. 245798355, The quotation is a formal contract between Jiangsu Caina Medical 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 Jiangsu Caina Medical Co., Ltd.

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



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