TÜVRheinland®
Precisely Right.

2023-08-22

To Whom It May Concern

TÜV Rheinland (Shanghai) Co., Ltd. confirms that the manufacturer **Jining Orodeka Medical Equipment Co., Ltd.** has lodged an application for conformity assessment based on MDR (EU) 2017/745 annex IX Chapter I.

The manufacturer signed the MDR certification contract on **2022-08-01**, Quotation No. **245779788**, The quotation is a formal contract between the manufacturer and TÜV Rheinland (Shanghai) Co., Ltd.

Products covered by the application are listed in the attached Product List and Application dated **2022-10-18.**

Concerning MDD Certificate No：**DD 60132717 0001**, expiry date: **2023-04-11**, TÜV Rheinland (Shanghai) Co., Ltd. will continue to do MDD surveillance audit for the manufacturer.

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)

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

Tony Chen

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