

2024-03-06

To Whom It May Concern

TÜV Rheinland (Shanghai) Co., Ltd. confirms that the manufacturer Wuxi Exanovo Medical Instrument 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 60140917 0001, expiry date: 2024-05-27.

Wuxi Exanovo Medical Instrument Co., Ltd. signed the MDR certification contract on 2024-03-04, Quotation No. 245831792, The quotation is a formal contract between Wuxi Exanovo Medical Instrument 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 Wuxi Exanovo Medical Instrument Co., Ltd.

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



Mr. Tony Chen
Location Field Manager
Medical Services

TÜV Rheinland
(Shanghai) Co., Ltd.

TUV Building,
No. 177, Lane 777,
West Guangzhong Road,
Shanghai 200072,
P.R.China

Tel. +86 21 6108 1188
Fax +86 21 6108 1099
+86 21 6108 1199

Hotline
800 999 3668/400 883 1300
service-gc@tuv.com

www.tuv.com