

# EU Certificate

## Quality Management System REGULATION (EU) 2017/745 on Medical Devices Annex IX Chapter I, Section 2 and 3 and Chapter III

Registration No.: HZ 2161305-1  
Manufacturer: Jining Orodeka Medical Equipment Co., Ltd.  
West 15 Floor, XinchengFazhan East Building, Beihu District,  
Jining,  
272000 Shandong  
P.R. China  
EUDAMED Single Registration No.: CN-MF-000034133  
Products: Products of class IIa:  
Q010507 - ENDODONTIC INSTRUMENTS (CANAL  
ENLARGERS, FILES, RASPS, ETC.), SINGLE-USE  
Authorized representative(s): ORODEKA S.R.L.  
VIA ANDREA DEL CASTAGNO, 9 50132 FIRENZE (FI)

Certificate history		
Revision:	Description:	Issue date:
0	Initial certification	2025-05-29

The Notified Body hereby declares that the requirements of Annex IX, Chapter I, Section 2 and 3 of the REGULATION (EU) 2017/745 have been met for the listed products. The above named manufacturer has established and applies a quality management system, which is subject to periodic surveillance, defined by Annex IX, Chapter I, Section 3 of the aforementioned regulation. The requirements of Annex IX, Chapter III are fulfilled.

If class III devices or class IIb implantable devices referred to in the second subparagraph of Article 52(4) are covered by this certificate an EU technical documentation assessment certificate according to Chapter II, Section 4.9 is required before placing them on the market.

Report No.: 244469962-200  
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Issue date: 2025-05-29

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This certificate can be validated on <https://www.certipedia.com>

TÜV Rheinland LGA Products GmbH is a Notified Body according to REGULATION (EU) 2017/745 concerning medical devices with the identification number 0197.



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