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 2026331-1
Manufacturer:	Changzhou Yimeng Medical Supplies Co., Ltd. 30# Qianbianzhuang, Henglin Town, Wujin, Changzhou 213101 Jiangsu P.R. China
EUDAMED Single Registration No.:	CN-MF-000036224
Products:	Products of class I, sterile: Q010508- DENTAL SURGERY INSTRUMENT KITS, SINGLE-USE Q010504- DENTISTRY MIRRORS AND STYLETS, SINGLE-USE Q010599- DENTAL INSTRUMENTS, SINGLE-USE - OTHER Q019003- DENTAL FLOSS AND OTHER DEVICES FOR ORAL HYGIENE (FOR PROFESSIONAL USE) The scope of certification is limited to the aspects relating to establishing, securing and maintaining sterile conditions
Authorized representative(s):	Caretechion GmbH Niederrheinstraße , 71 40474 Düsseldorf, Germany

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.:	326096857-200
Effective date:	2025-06-03
Expiry date:	2029-11-26
Issue date:	2025-06-03

Fuxiu Sheng
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

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

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Certificate history		
Revision:	Description:	Issue date:
0	Initial certification	2024-11-27
1	SRN number Correction	2025-06-03

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