EU Certificate

Production Quality Assurance
REGULATION (EU) 2017/745 on Medical Devices, Annex XI, Part A

TÜVRheinland®

Registration No.:	DZ 2138755-1
Manufacturer:	**United Dental Changzhou** B1, C1, D2, F2, No. 9 Changyang Road, West Taihu Science and Technology Industrial Park Changzhou 213145 Jiangsu P.R. China
EUDAMED Single Registration No.:	CN-MF-000018453
Products:	Products of class IIa: Q010507 - ENDODONTIC INSTRUMENTS (CANAL ENLARGERS, FILES, RASPS, ETC.), SINGLE-USE L159004 - ENDODONTIC RASPS AND FILES, REUSABLE Products of class I, reusable surgical instruments: L159004 - ENDODONTIC RASPS AND FILES, REUSABLE The scope of certification is limited to the aspects relating to the reuse of the device, in particular cleaning, disinfection, sterilization, maintenance and functional testing and the related instructions for use
Authorised representative(s):	Caretechion GmbH Niederrheinstr. 71,40474 Düsseldorf, Germany

Certificate history		
Revision:	Description:	Issue date:
0	Initial Revision	2023-06-28

The Notified Body hereby declares that the requirements of Annex XI, Part A of the REGULATION (EU) 2017/745 have been met for the listed products. The above named manufacturer has established and applies a production quality assurance, which is subject to periodic surveillance, defined by Annex XI, Part A, Section 7 of the aforementioned regulation. If class III devices or class IIb devices are covered by this certificate, an EU type-examination certificate in accordance with Annex X of the aforementioned regulation is required before placing them on the market.

Report No.:	244437083-200
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Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-MDR-091

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle

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

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