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 1470094-1
Manufacturer:	Gebr. Brasseler GmbH & Co. KG Trophagener Weg 25 32657 Lemgo Germany
EUDAMED Single Registration No.:	DE-MF-000006446
Products:	Products of class IIa: L090999 ORTHOPAEDIC SURGERY CUTTING INSTRUMENTS, REUSABLE - OTHER L159004 ENDODONTIC RASPS AND FILES, REUSABLE Q010199 CONSERVATIVE DENTISTRY AND ENDODONTICS DEVICES - OTHER Q010501 DENTAL BURS AND ABRASIVE DISKS, SINGLE-USE Q010507 ENDODONTIC INSTRUMENTS (CANAL ENLARGERS, FILES, RASPS, ETC.), SINGLE-USE V0199 CUTTING DEVICES, SINGLE-USE - OTHER Q010399 SURGICAL DENTAL DEVICES – OTHER P091305 BONE SAWS, SINGLE-USE Q010102 ROOT CANAL FILLING DEVICES

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.:	1133391-20
Effective date:	2024-03-14
Expiry date:	2026-02-28
Issue date:	2024-03-14

Dipl.-Ing. U. Frenkert
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

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.

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-MDR-091

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Precisely Right.

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Annex IX Chapter I, Section 2 and 3 and Chapter III

Registration No.:	HZ 1470094-1
Manufacturer:	Gebr. Brasseler GmbH & Co. KG Trophagener Weg 25 32657 Lemgo Germany
EUDAMED Single Registration No.:	DE-MF-000006446
	Products of class I, sterile: Q010199 CONSERVATIVE DENTISTRY AND ENDODONTICS DEVICES - OTHER L159004 ENDODONTIC RASPS AND FILES, REUSABLE The scope of certification is limited to the aspects relating to establishing, securing and maintaining sterile conditions.
	Products of class I, reusable surgical instruments: Q010199 CONSERVATIVE DENTISTRY AND ENDODONTICS DEVICES - OTHER 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.
Authorized representative(s):	N/A

Report No.:	1133391-20
Effective date:	2024-03-14
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Registration No.: HZ 1470094-1

Manufacturer: Gebr. Brasseler GmbH & Co. KG
Trophagener Weg 25
32657 Lemgo
Germany

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Certificate history		
Revision:	Description:	Issue date:
0	Initial certification	2021-07-21
1	Scope extension, Products of class IIa “Q010399 Surgical Dental Devices – Others”	2023-01-24
2	Scope extension, Products of class IIa “P091305 Bone Saws, Single Use”	2023-11-24
3	Scope extension, Products of class I, sterile and Products of class I reusable surgical instruments “L159004 ENDODONTIC RASPS AND FILES, REUSABLE”; Products of class IIa “Q010102 ROOT CANAL FILLING DEVICES”	2024-03-14

Report No.: 1133391-20

Effective date: 2024-03-14

Expiry date: 2026-02-28

Issue date: 2024-03-14

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