EU Certificate

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

TÜVRheinland®

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 - Others
L159004 Endodontic Raspatories and Files
Q010199 Devices for Conservative Dentistry and Endodontics - Others
Q010501 Dental Burs and Abrasive Disks, Single-Use
Q010507 Endodontic Instrumentary, Single-Use (Enlargers, Files, Rasps, etc.)
V0199 Cutting Devices, Single-Use - Others
Q010399 Surgical Dental Devices - Others

Products of class I, sterile:
Q010199 Devices for Conservative Dentistry and Endodontics - Others

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 Devices for Conservative Dentistry and Endodontics - Others

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

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.: 1111397-20

Effective date: 2023-01-24

Expiry date: 2026-02-28

Issue date: 2023-01-24

TÜV Rheinland LGA Products GmbH TÜVRheinland Prüfzertifizierungsstelle

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

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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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Authorised representative(s): N/A

Certificate history		
Revision:	Description:	Issue date:
1	Initial Revision	2021-07-21
2	Scope extension, Products of class IIa "Q010399 Surgical Dental Devices – Others"	2023-01-24

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