

# 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 - 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  
P091305 Bone Saws, Single-Use

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

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.: 1147098-10

Effective date: 2023-11-24

Expiry date: 2026-02-28

Issue date: 2023-11-24



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

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

EUDAMED Single  
Registration No.: DE-MF-000006446

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

Authorized representative(s): N/A

Certificate history		
Revision:	Description:	Issue date:
1	Initial certification	2021-07-21
2	Scope extension, Products of class IIa "Q010399 Surgical Dental Devices – Others"	2023-01-24
3	Scope extension, Products of class IIa "P091305 Bone Saws, Single-Use"	2023-11-24

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