



Benannt durch/Designated by  
Zentralstelle der Länder  
für Gesundheitsschutz  
bei Arzneimitteln und  
Medizinprodukten  
www.zlg.de  
BS-MDR-099



Product Service

## EU Quality Management System Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III  
(Implantable Class IIb Devices and Class III Devices)

**No. G12 025701 0096 Rev. 02**

### Manufacturer:

**B. Braun Surgical, S.A.**

Ctra. de Terrassa, 121  
08191 Rubí (Barcelona)  
SPAIN

SRN Manufacturer - ES-MF-000002083

The Certification Body of TÜV SÜD Product Service GmbH certifies that the manufacturer has established, documented and implemented a quality management system as described in Article 10 (9) of the Regulation (EU) 2017/745 on medical devices. Details on device categories covered by the quality management system are described on the following page(s).

The Report referenced below summarises the result of the assessment and includes reference to relevant CS, harmonized standards and test reports. The conformity assessment has been carried out according to Annex IX Chapter I and III of this regulation with a positive result.

The certified quality management system is subject to periodical surveillance by TÜV SÜD Product Service GmbH.

In order to place the devices on the market with CE-marking, an EU Technical Documentation Assessment Certificate pursuant to Annex IX chapter II is necessary in addition to this EU Quality Management System Certificate. All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see:

[www.tuvsud.com/ps-cert?q=cert:G12 025701 0096 Rev. 02](http://www.tuvsud.com/ps-cert?q=cert:G12 025701 0096 Rev. 02)

**Report No.:** 713312458

**Preceding Certificate No.:** G12 025701 0096 Rev. 01

**Valid from:** 2024-01-19

**Valid until:** 2027-07-18

**Date of Initial Issuance:** 2022-07-19

Christoph Dicks  
Head of Certification/Notified Body

**Issue date:** 2024-01-19



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**Classification:** Class III  
**Device Group:** H010101 - ABSORBABLE SYNTHETIC SUTURES  
**Intended Purpose:** -

**Classification:** Class III  
**Device Group:** H900101 - GLUES  
**Intended Purpose:** -

**Classification:** Class III  
**Device Group:** P900202 - POLYPROPYLENE SURGICAL MESHES  
**Intended Purpose:** -

**The validity of this certificate** -  
**depends on conditions and/or**  
**is limited to the following:**

### Revision History:

| Rev. | Dated      | Report              | Description                                      |
|------|------------|---------------------|--|
| 00   | 2022-07-19 | 713257305_713194732 | -  |
| 01   | 2023-08-28 | 713273649           | Supplemented: Device(s)/group of device(s) added |
| 02   | 2024-01-19 | 713312458           | Supplemented: Device(s)/group of device(s) added |