



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 012974 0651 Rev. 01**

### Manufacturer:

**B. Braun Melsungen AG**

Carl-Braun-Str. 1  
34212 Melsungen  
GERMANY

SRN Manufacturer - DE-MF-000000201

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, Certification, Validation and Verification Regulations TÜV SÜD Group have to be complied with.

For details and certificate validity see: [www.tuvsud.com/ps-cert?q=cert:G12 012974 0651 Rev. 01](http://www.tuvsud.com/ps-cert?q=cert:G12 012974 0651 Rev. 01)

### Report No.:

713316029 / 713332278

### Preceding Certificate No.:

G12 012974 0651 Rev. 00

### Valid from:

2024-04-15

### Valid until:

2028-10-11

### Date of Initial Issuance:

2023-10-12

Christoph Dicks

### Issue date:

2024-04-15

Head of Certification/Notified Body

Effective



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**No. G12 012974 0651 Rev. 01**

**Classification:** Class III  
**Device Group:** N020101 - PERIDURAL / EPIDURAL SPINAL CATHETERS AND KITS  
**Intended Purpose:** -

**Classification:** Class III  
**Device Group:** A010301 - SPINAL AND EPIDURAL ANAESTHESIA NEEDLES AND KITS  
**Intended Purpose:** -

**Classification:** Class III  
**Device Group:** V0999 - FLUIDS/GASES FOR CLINICAL/THERAPEUTICAL USE  
- OTHER  
**Intended Purpose:** -

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

### Revision History:

Rev.	Dated	Report	Description
00	2023-10-12	713303196	Initial issuance
01	2024-04-15	713316029 / 713332278	Supplemented: Device(s)/group of device(s) added

Effective