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

Product Service

EU Technical Documentation Assessment Certificate (MDR)

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

No. G70 053268 0093 Rev. 00

Manufacturer:

RAUMEDIC AG
Hermann-Staudinger-Strasse 2
95233 Helmbrechts
GERMANY

SRN Manufacturer - DE-MF-000006155

The Certification Body of TÜV SÜD Product Service GmbH certifies that the manufacturer has drawn up and presented a Technical Documentation according to Annex II and III of the Regulation (EU) 2017/745 on medical devices. Details on devices covered by the Technical Documentation 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 technical documentation assessment included an assessment of the clinical evaluation assessment.
The conformity assessment has been carried out according to Annex IX chapter II of this regulation with a positive result.
Changes to the approved device, where such changes could affect the safety and performance of the device or the conditions prescribed for use of the device, shall require approval from the notified body TÜV SÜD Product Service GmbH.
In order to place the devices on the market with CE-marking, an EU Quality Management System Certificate pursuant to Annex IX chapters I and III is necessary in addition to this EU Technical Documentation Assessment 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:G70 053268 0093 Rev. 00

Report No.: 713232309

Valid from: 2025-01-15
Valid until: 2030-01-14

Christoph Dicks
Head of Certification/Notified Body

Issue date: 2025-01-15

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No. G70 053268 0093 Rev. 00

Classification:	Class III
Device Group:	Z12109085 - VARIOUS NEUROLOGY AND NEUROSURGERY INSTRUMENTS - SPECIFIC MATERIALS
Basic UDI-DI:	4057834BOLT0026T6
Intended Purpose:	Raumedic DRILL KITs are neurosurgical instruments that serve to introduce a bore into the skull with the help of an appropriate drilling machine in order to subsequently enable secure fixation of the Raumedic BOLT in the cranial vault. Raumedic BOLT KITs are used in the application of catheters in neurosurgical areas. The system secures the catheter in position and acts as a seal against the outside world. Raumedic BOLT-DRILL KITs are a combination of BOLT KIT and DRILL KIT.
Device(s):	BOLT KIT

Classification:	Class III
Device Group:	Z12109085 - VARIOUS NEUROLOGY AND NEUROSURGERY INSTRUMENTS - SPECIFIC MATERIALS
Basic UDI-DI:	4057834BOLTDRILL0026JJ
Intended Purpose:	Raumedic DRILL KITs are neurosurgical instruments that serve to introduce a bore into the skull with the help of an appropriate drilling machine in order to subsequently enable secure fixation of the Raumedic BOLT in the cranial vault. Raumedic BOLT KITs are used in the application of catheters in neurosurgical areas. The system secures the catheter in position and acts as a seal against the outside world. Raumedic BOLT-DRILL KITs are a combination of BOLT KIT and DRILL KIT.
Device(s):	BOLT-DRILL KIT

Classification:	Class III
Device Group:	Z12109085 - VARIOUS NEUROLOGY AND NEUROSURGERY INSTRUMENTS - SPECIFIC MATERIALS
Basic UDI-DI:	4057834DRILL00266G
Intended Purpose:	Raumedic DRILL KITs are neurosurgical instruments that serve to introduce a bore into the skull with the help of an appropriate drilling machine in order to subsequently enable secure fixation of the Raumedic BOLT in the cranial vault. Raumedic BOLT KITs are used in the application of catheters in neurosurgical areas. The system secures the catheter in position and acts as a seal against the outside world. Raumedic BOLT-DRILL KITs are a combination of BOLT KIT and DRILL KIT.
Device(s):	DRILL KIT

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No. G70 053268 0093 Rev. 00

Medical device Name	Individual Article number of the Device	Device Basic UDI-DI
BOLT KIT CH9	091688-002	4057834BOLT0026T6
BOLT KIT CH5	091868-002	4057834BOLT0026T6
BOLT KIT PTO	096026-001	4057834BOLT0026T6
BOLT KIT PTO 2L	096076-001	4057834BOLT0026T6

Medical device Name	Individual Article number of the Device	Device Basic UDI-DI
BOLT-DRILL KIT CH5	091888-001	4057834BOLTDRILL0026JJ
BOLT-DRILL KIT CH9	091898-001	4057834BOLTDRILL0026JJ
BOLT-DRILL KIT PTO	092380-001	4057834BOLTDRILL0026JJ
BOLT-DRILL KIT VP 16	092969-001	4057834BOLTDRILL0026JJ

Medical device Name	Individual Article number of the Device	Device Basic UDI-DI
DRILL KIT CH9	091668-002	4057834DRILL00266G
DRILL KIT CH5	091878-002	4057834DRILL00266G

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

Revision History:

Rev.	Dated	Report	Description
00	2025-01-15	713232309	Initial issuance

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