ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

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 010066 0440 Rev. 01

Manufacturer:

AESCULAP AG
Am Aesculap-Platz
78532 Tuttlingen
GERMANY

SRN Manufacturer: DE-MF-000005504

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 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:G70 010066 0440 Rev. 01

Report No.: 713236216

Preceding Certificate No.: G70 010066 0440 Rev. 00

Valid from: 2022-03-18
Valid until: 2026-06-30

Date of Initial Issuance: 2021-07-01

Issue date: 2022-03-18

Head of Certification/Notified Body

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123
TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

TÜV®

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

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

TÜV SÜD 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 010066 0440 Rev. 01

Classification: III

Device Group: P900403 - NON-RESORBABLE FILLING AND RECONSTRUCTION DEVICES

Basic UDI-DI: 4039239000001401ZR

Intended Purpose: Neuro-Patch® is used in neurosurgery as dura mater replacement.

Device(s): Neuro-Patch®

1064002 NEURO-PATCH 12X14CM
1064010 NEURO-PATCH 6X14CM
1064020 NEURO-PATCH 8X9CM
1064029 NEURO-PATCH 6X8CM
1064037 NEURO-PATCH 4X10CM
1064040 NEURO-PATCH 5X6CM
1064045 NEURO-PATCH 4X5CM
1064053 NEURO-PATCH 2X10CM
1064061 NEURO-PATCH 1.5X3CM
1064110 NEURO-PATCH 4X5CM SGL.PIECE
1064122 NEURO-PATCH 2X10CM SGL.PIECE
1064123 NEURO-PATCH 1.5X3CM SGL.PIECE

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

Revision History:

Rev.	Dated	Report
00	2021-07-01	713197662

.

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123
TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

TÜV®