



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 010066 0441 Rev. 01

Manufacturer: **AESCALAP 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 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_010066_0441_Rev._01

Report No.: 713260697
Preceding Certificate No.: G12 010066 0441 Rev. 00
Valid from: 2023-04-26
Valid until: 2026-06-30
Date of Initial Issuance: 2021-07-01

Christoph Dicks
Head of Certification/Notified Body

Issue date: 2023-04-26



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Classification: Class III
Device Group: P900402 - RESORBABLE FILLING AND RECONSTRUCTION DEVICES

Intended Purpose: -

Classification: Class III
Device Group: P900403 - NON-RESORBABLE FILLING AND RECONSTRUCTION DEVICES

Intended Purpose: -

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

Revision History:

Rev.	Dated	Report	Description
00	2021-07-01	713203410	-
01	2023-04-26	713260697	Supplemented: Device(s)/group of device(s) added