



EU Quality Management System Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III
(Class I Devices in sterile condition, with measuring function or reusable surgical instruments)

No. G11 010066 0437 Rev. 02

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 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. As applicable the involvement of the notified body is limited to the aspects relating to:

- establishing, securing and maintaining sterile conditions,
- conformity of the devices with the metrological requirements,
- reuse of the device, in particular cleaning, disinfection, sterilization, maintenance and functional testing and the related instructions for use.

The certified quality management system is subject to periodical surveillance by TÜV SÜD Product Service GmbH. 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:G11 010066 0437 Rev. 02](http://www.tuvsud.com/ps-cert?q=cert:G11_010066_0437_Rev._02)

Report No.: 713203409
Preceding Certificate No.: G11 010066 0437 Rev. 01
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Valid until: 2025-07-09
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Christoph Dicks
Head of Certification/Notified Body

Issue date: 2022-12-19



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Classification:	I
Device Group:	A019009 - DRAINAGE NEEDLES
Device Properties:	MDS 1006 - Reusable surgical instruments
Classification:	I
Device Group:	G020401 - HAEMORRHOID LIGATURE SETS
Device Properties:	MDS 1006 - Reusable surgical instruments
Classification:	I
Device Group:	H020303 - CLIP APPLIERS
Device Properties:	MDS 1006 - Reusable surgical instruments
Classification:	I
Device Group:	H030201 - MULTIPLE CLIP APPLIERS FOR VIDEOSURGERY
Device Properties:	MDS 1006 - Reusable surgical instruments
Classification:	I
Device Group:	L0101 - SURGICAL SCALPELS, REUSABLE
Device Properties:	MDS 1006 - Reusable surgical instruments
Classification:	I
Device Group:	L0102 - SURGICAL KNIVES, REUSABLE
Device Properties:	MDS 1006 - Reusable surgical instruments
Classification:	I
Device Group:	L0103 - DERMOTOMES AND BLADES, REUSABLE
Device Properties:	MDS 1006 - Reusable surgical instruments
Classification:	I
Device Group:	L0104 - SURGICAL SCISSORS, REUSABLE
Device Properties:	MDS 1006 - Reusable surgical instruments
Classification:	I
Device Group:	L0107 - SURGICAL SAWS AND BLADES, REUSABLE
Device Properties:	MDS 1006 - Reusable surgical instruments



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Classification: I
Device Group: L0201 - NEEDLES AND APPLICATORS FOR LIGATURES, REUSABLE
Device Properties: MDS 1006 - Reusable surgical instruments

Classification: I
Device Group: L0202 - SUTURE NEEDLES, REUSABLE
Device Properties: MDS 1006 - Reusable surgical instruments

Classification: I
Device Group: L0205 - NEEDLE HOLDERS, REUSABLE
Device Properties: MDS 1006 - Reusable surgical instruments

Classification: I
Device Group: L0206 - GROOVED PROBES, REUSABLE
Device Properties: MDS 1006 - Reusable surgical instruments

Classification: I
Device Group: L0299 - SUTURE INSTRUMENTS, REUSABLE - OTHER
Device Properties: MDS 1006 - Reusable surgical instruments

Classification: I
Device Group: L031101 - FISTULA PROBES, REUSABLE
Device Properties: MDS 1006 - Reusable surgical instruments

Classification: I
Device Group: L0312 - SURGICAL TROCAR, REUSABLE
Device Properties: MDS 1006 - Reusable surgical instruments

Classification: I
Device Group: L0313 - GENERAL SURGERY FORCEPS, REUSABLE
Device Properties: MDS 1006 - Reusable surgical instruments



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Classification:	I
Device Group:	L0314 - GENERAL SURGERY SPREADERS AND SPATULAS, REUSABLE
Device Properties:	MDS 1006 - Reusable surgical instruments
Classification:	I
Device Group:	L0315 - GENERAL SURGERY DISSECTORS, REUSABLE
Device Properties:	MDS 1006 - Reusable surgical instruments
Classification:	I
Device Group:	L0408 - ABDOMINAL SURGERY SPECIAL FORCEPS, REUSABLE
Device Properties:	MDS 1006 - Reusable surgical instruments
Classification:	I
Device Group:	L0409 - ABDOMINAL SURGERY DILATORS AND SPREADERS, REUSABLE
Device Properties:	MDS 1006 - Reusable surgical instruments
Classification:	I
Device Group:	L041001 - LIVER AND BILIARY ROUTES SURGICAL PROBES, MULTIPURPOSE
Device Properties:	MDS 1006 - Reusable surgical instruments
Classification:	I
Device Group:	L0499 - ABDOMINAL SURGERY INSTRUMENTS, REUSABLE - OTHER
Device Properties:	MDS 1006 - Reusable surgical instruments
Classification:	I
Device Group:	L0508 - OBSTETRICS INSTRUMENTS, REUSABLE
Device Properties:	MDS 1006 - Reusable surgical instruments
Classification:	I
Device Group:	L0509 - GYNECOLOGICAL SURGERY INSTRUMENTS, REUSABLE
Device Properties:	MDS 1006 - Reusable surgical instruments MDS 1010 - Devices with a measuring function



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Classification:	I
Device Group:	L0590 - OBSTETRICS AND GYNECOLOGY INSTRUMENTS, REUSABLE - VARIOUS
Device Properties:	MDS 1006 - Reusable surgical instruments
Classification:	I
Device Group:	L060502 - NON-ENDOSCOPIC UROLOGY SPREADERS, REUSABLE
Device Properties:	MDS 1006 - Reusable surgical instruments
Classification:	I
Device Group:	L0606 - NON-ENDOSCOPIC UROLOGY FORCEPS, REUSABLE
Device Properties:	MDS 1006 - Reusable surgical instruments
Classification:	I
Device Group:	L070702 - CARDIAC DILATORS AND RETRACTORS, REUSABLE
Device Properties:	MDS 1006 - Reusable surgical instruments
Classification:	I
Device Group:	L0708 - VASCULAR SURGERY INSTRUMENTS, REUSABLE
Device Properties:	MDS 1006 - Reusable surgical instruments
Classification:	I
Device Group:	L0801 - COSTOTOMES, REUSABLE
Device Properties:	MDS 1006 - Reusable surgical instruments
Classification:	I
Device Group:	L0804 - STERNOTOMY SURGICAL INSTRUMENTS, REUSABLE
Device Properties:	MDS 1006 - Reusable surgical instruments
Classification:	I
Device Group:	L080502 - PULMONARY CLAMPS, REUSABLE
Device Properties:	MDS 1006 - Reusable surgical instruments
Classification:	I
Device Group:	L080602 - THORACIC SURGERY SPREADERS, REUSABLE
Device Properties:	MDS 1006 - Reusable surgical instruments



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Classification:	I
Device Group:	L0807 - THORACIC SURGERY SPATULAS, REUSABLE
Device Properties:	MDS 1006 - Reusable surgical instruments
Classification:	I
Device Group:	L0899 - THORACIC SURGERY INSTRUMENTS, REUSABLE - OTHER
Device Properties:	MDS 1006 - Reusable surgical instruments
Classification:	I
Device Group:	L0901 - ORTHOPAEDIC SURGERY SPOONS AND CURETTES, REUSABLE
Device Properties:	MDS 1006 - Reusable surgical instruments
Classification:	I
Device Group:	L0902 - ORTHOPAEDIC SURGERY LEVERS, REUSABLE
Device Properties:	MDS 1006 - Reusable surgical instruments
Classification:	I
Device Group:	L0904 - OSTEOTOMES AND SCALPELS, REUSABLE
Device Properties:	MDS 1006 - Reusable surgical instruments
Classification:	I
Device Group:	L090901 - BONE CUTTERS, REUSABLE
Device Properties:	MDS 1006 - Reusable surgical instruments
Classification:	I
Device Group:	L091001 - INSTRUMENTS FOR INSERTION AND EXTRACTION OF MATERIALS FOR OSTEOSYNTHESIS, REUSABLE
Device Properties:	MDS 1006 - Reusable surgical instruments
Classification:	I
Device Group:	L0911 - ORTHOPAEDIC PROSTHETICS INSTRUMENTS, REUSABLE
Device Properties:	MDS 1006 - Reusable surgical instruments
Classification:	I
Device Group:	L0912 - ORTHOPAEDIC RASPS AND FILES, REUSABLE
Device Properties:	MDS 1006 - Reusable surgical instruments



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Device Group:	L0913 - ORTHOPAEDIC SURGERY FORCEPS, REUSABLE
Device Properties:	MDS 1006 - Reusable surgical instruments
Classification:	I
Device Group:	L0915 - SPREADERS AND RETRACTORS FOR ORTHOPAEDIC SURGERY, REUSABLE
Device Properties:	MDS 1006 - Reusable surgical instruments
Classification:	I
Device Group:	L0999 - ORTHOPAEDIC AND TRAUMATOLOGICAL SURGERY INSTRUMENTS, REUSABLE - OTHER
Device Properties:	MDS 1006 - Reusable surgical instruments MDS 1010 - Devices with a measuring function
Classification:	I
Device Group:	L1102 - NEUROSURGERY SPATULAS AND DISSECTORS, REUSABLE
Device Properties:	MDS 1006 - Reusable surgical instruments
Classification:	I
Device Group:	L1105 - NEUROSURGERY SPREADERS AND RETRACTORS, REUSABLE
Device Properties:	MDS 1006 - Reusable surgical instruments
Classification:	I
Device Group:	L1106 - NEUROSURGERY FORCEPS, REUSABLE
Device Properties:	MDS 1006 - Reusable surgical instruments
Classification:	I
Device Group:	L1199 - NEUROSURGERY INSTRUMENTS, REUSABLE-OTHER
Device Properties:	MDS 1006 - Reusable surgical instruments
Classification:	I
Device Group:	L1201 - LAPAROSCOPIC AND THORACOSCOPIC SURGERY DISSECTORS, REUSABLE
Device Properties:	MDS 1006 - Reusable surgical instruments



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Classification: I
Device Group: L1204 - LAPAROSCOPIC AND THORACOSCOPIC SURGERY
FORCEPS REUSABLE
Device Properties: MDS 1006 - Reusable surgical instruments

Classification: I
Device Group: L1205 - LAPAROSCOPIC AND THORACOSCOPIC SURGERY
NEEDLE HOLDERS, REUSABLE
Device Properties: MDS 1006 - Reusable surgical instruments

Classification: I
Device Group: L1206 - LAPAROSCOPIC AND THORACOSCOPIC SURGERY
SPREADERS AND RETRACTORS, REUSABLE
Device Properties: MDS 1006 - Reusable surgical instruments

Classification: I
Device Group: L1401 - PHARYNX SURGERY INSTRUMENTS, REUSABLE
Device Properties: MDS 1006 - Reusable surgical instruments

Classification: I
Device Group: L1402 - NASAL AND PARANASAL CAVITY SURGERY
INSTRUMENTS, REUSABLE
Device Properties: MDS 1006 - Reusable surgical instruments

Classification: I
Device Group: L1403 - LARYNX SURGERY INSTRUMENTS, REUSABLE
Device Properties: MDS 1006 - Reusable surgical instruments

Classification: I
Device Group: L140401 - TRACHEAL DILATORS, REUSABLE
Device Properties: MDS 1006 - Reusable surgical instruments

Classification: I
Device Group: L1405 - EAR SURGERY INSTRUMENTS, REUSABLE
Device Properties: MDS 1006 - Reusable surgical instruments

Classification: I
Device Group: L1406 - ENT OSTEOTOMES AND SCALPELS, REUSABLE
Device Properties: MDS 1006 - Reusable surgical instruments



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Device Group:	L1490 - ENT INSTRUMENTS, REUSABLE - VARIOUS
Device Properties:	MDS 1006 - Reusable surgical instruments
Classification:	I
Device Group:	L1501 - ODONTOSTOMATOLOGY OSTEOTOMES AND SCALPELS, REUSABLE
Device Properties:	MDS 1006 - Reusable surgical instruments
Classification:	I
Device Group:	L1502 - ODONTOSTOMATOLOGY SPREADERS AND RETRACTORS, REUSABLE
Device Properties:	MDS 1006 - Reusable surgical instruments
Classification:	I
Device Group:	L1503 - ODONTOSTOMATOLOGY FORCEPS, REUSABLE
Device Properties:	MDS 1006 - Reusable surgical instruments
Classification:	I
Device Group:	L1505 - ODONTOSTOMATOLOGY LEVERS, REUSABLE
Device Properties:	MDS 1006 - Reusable surgical instruments
Classification:	I
Device Group:	L150702 - ORTHODONTIC PLIERS, REUSABLE
Device Properties:	MDS 1006 - Reusable surgical instruments
Classification:	I
Device Group:	L1590 - ODONTOSTOMATOLOGY INSTRUMENTS, REUSABLE - VARIOUS
Device Properties:	MDS 1006 - Reusable surgical instruments
Classification:	I
Device Group:	L160201 - DENTAL MIRRORS AND HANDLES, REUSABLE
Device Properties:	MDS 1006 - Reusable surgical instruments
Classification:	I
Device Group:	L1705 - OPHTHALMOLOGY PROBES, REUSABLE
Device Properties:	MDS 1006 - Reusable surgical instruments



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Classification: I
Device Group: T030199 - COVERS, INSTRUMENTS AND EQUIPMENT - OTHER

Device Properties: MDS 1005.1 - Ethylene Oxide sterilization

Classification: I
Device Group: V0199 - CUTTING DEVICES, SINGLE-USE - OTHER
Device Properties: MDS 1005.2 - Sterilisation by irradiation

Classification: I
Device Group: V0302 - CLINICAL DIMENSIONAL PARAMETERS MEASURING DEVICES
Device Properties: MDS 1006 - Reusable surgical instruments
MDS 1010 - Devices with a measuring function

Classification: I
Device Group: V0399 - MEASUREMENT DEVICES - OTHER
Device Properties: MDS 1006 - Reusable surgical instruments
MDS 1010 - Devices with a measuring function

Classification: I
Device Group: V9099 - VARIOUS DEVICES NOT INCLUDED IN OTHER CLASSES - OTHER
Device Properties: MDS 1005.2 - Sterilisation by irradiation

Classification: I
Device Group: Z1201 - GENERAL AND MULTIDISCIPLINARY SURGERY INSTRUMENTS
Device Properties: MDS 1005.1 - Ethylene Oxide sterilization
MDS 1005.2 - Sterilisation by irradiation

Classification: I
Device Group: Q0299 - OPHTHALMIC DEVICES - OTHER
Device Properties: MDS 1005.2 - Sterilisation by irradiation



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

Revision History:

Rev.	Dated	Report
00	2020-07-10	713175266
01	2022-12-15	713203409