



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

Valid from: 2022-12-19
Valid until: 2025-07-09

Date of Initial Issuance: 2020-07-10

Christoph Dicks
Head of Certification/Notified Body

Issue date: 2022-12-19



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

- | | |
|---------------------------|---|
| 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 |



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

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



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

| | |
|---------------------------|--|
| 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 |



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

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



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

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



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

Classification: I
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



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

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



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

- | | |
|---------------------------|--|
| Classification: | I |
| 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 |



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
(Class I Devices in sterile condition, with measuring function or reusable surgical instruments)

No. G11 010066 0437 Rev. 02

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



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

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 |