



## EU Quality Management System Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III  
(Class IIa and Class IIb Devices)

**No. G10 010066 0438 Rev. 04**

**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. The quality management system assessment was accompanied by the assessment of technical documentation for devices selected on a representative basis. The certified quality management system is subject to periodical surveillance by TÜV SÜD Product Service GmbH. The surveillance assessment shall also include an assessment of the technical documentation for the device or devices concerned on the basis of further representative samples. 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:G10 010066 0438 Rev. 04](http://www.tuvsud.com/ps-cert?q=cert:G10_010066_0438_Rev._04)

**Report No.:** 713218567 / 713218653 / 713218808 / 713230390 / 713303316

**Preceding Certificate No.:** G10 010066 0438 Rev. 03

**Valid from:** 2023-11-07

**Valid until:** 2025-07-09

**Date of Initial Issuance:** 2020-07-10

Christoph Dicks  
Head of Certification/Notified Body

**Issue date:** 2023-11-07



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### No. G10 010066 0438 Rev. 04

**Classification:** Class IIa  
**Device Group:** L030101 - SUCTION AND IRRIGATION SURGICAL CANNULAS AND HANDPIECES, REUSABLE

**Intended Purpose:** -

**Classification:** Class IIa  
**Device Group:** L031309 - SUTURE NEEDLE PASSERS, REUSABLE  
**Intended Purpose:** -

**Classification:** Class IIa  
**Device Group:** L031401 - GENERAL SURGERY SPREADERS AND RETRACTORS, REUSABLE  
**Intended Purpose:** -

**Classification:** Class IIa  
**Device Group:** L040901 - ABDOMINAL SPREADERS, REUSABLE  
**Intended Purpose:** -

**Classification:** Class IIa  
**Device Group:** L060502 - NON-ENDOSCOPIC UROLOGY SPREADERS, REUSABLE  
**Intended Purpose:** -

**Classification:** Class IIa  
**Device Group:** L070702 - CARDIAC DILATORS AND RETRACTORS, REUSABLE  
**Intended Purpose:** -

**Classification:** Class IIa  
**Device Group:** L080602 - THORACIC SURGERY SPREADERS, REUSABLE  
**Intended Purpose:** -

**Classification:** Class IIa  
**Device Group:** L090901 - BONE CUTTERS, REUSABLE  
**Intended Purpose:** -

**Classification:** Class IIa  
**Device Group:** L090901 - BONE CUTTERS, REUSABLE  
**Intended Purpose:** -



## EU Quality Management System Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III  
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**No. G10 010066 0438 Rev. 04**

<b>Classification:</b>	Class IIa
<b>Device Group:</b>	L110501 - VERTEBRAL SURGERY SPREADERS AND RETRACTORS, REUSABLE
<b>Intended Purpose:</b>	-
<b>Classification:</b>	Class IIa
<b>Device Group:</b>	L110503 - CRANIAL SURGERY SPREADERS AND RETRACTORS, REUSABLE
<b>Intended Purpose:</b>	-
<b>Classification:</b>	Class IIa
<b>Device Group:</b>	L149003 - ENT RETRACTORS, REUSABLE
<b>Intended Purpose:</b>	-
<b>Classification:</b>	Class IIa
<b>Device Group:</b>	L031201 - THORACIC TROCAR, REUSABLE
<b>Intended Purpose:</b>	-
<b>Classification:</b>	Class IIa
<b>Device Group:</b>	L031202 - ABDOMINAL TROCAR, REUSABLE
<b>Intended Purpose:</b>	-
<b>Classification:</b>	Class IIa
<b>Device Group:</b>	L031280 - SURGICAL TROCAR, REUSABLE - ACCESSORIES
<b>Intended Purpose:</b>	-
<b>Classification:</b>	Class IIa
<b>Device Group:</b>	A019001 - BLUNT NEEDLES
<b>Intended Purpose:</b>	-
<b>Classification:</b>	Class IIa
<b>Device Group:</b>	A070199 - ADAPTERS AND CONNECTORS - OTHER
<b>Intended Purpose:</b>	-
<b>Classification:</b>	Class IIa
<b>Device Group:</b>	C019019 - VESSEL STRIPPER SYSTEMS
<b>Intended Purpose:</b>	-



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<b>Classification:</b>	Class IIa
<b>Device Group:</b>	G020401 - HAEMORRHOID LIGATURE SETS
<b>Intended Purpose:</b>	-
<b>Classification:</b>	Class IIa
<b>Device Group:</b>	H030102 - SINGULAR CLIPS FOR OPEN SURGERY
<b>Intended Purpose:</b>	-
<b>Classification:</b>	Class IIa
<b>Device Group:</b>	H030201 - MULTIPLE CLIP APPLIERS FOR VIDEOSURGERY
<b>Intended Purpose:</b>	-
<b>Classification:</b>	Class IIa
<b>Device Group:</b>	H030201 - MULTIPLE CLIP APPLIERS FOR VIDEOSURGERY
<b>Intended Purpose:</b>	-
<b>Classification:</b>	Class IIa
<b>Device Group:</b>	K010101 - TROCAR, SINGLE-USE
<b>Intended Purpose:</b>	-
<b>Classification:</b>	Class IIa
<b>Device Group:</b>	K010201 - MINIMALLY INVASIVE SURGERY SURGICAL INSTRUMENTS, SINGLE-USE
<b>Intended Purpose:</b>	-
<b>Classification:</b>	Class IIa
<b>Device Group:</b>	K010201 - MINIMALLY INVASIVE SURGERY SURGICAL INSTRUMENTS, SINGLE-USE
<b>Intended Purpose:</b>	-
<b>Classification:</b>	Class IIa
<b>Device Group:</b>	K0104 - VERESS NEEDLES
<b>Intended Purpose:</b>	-



## EU Quality Management System Certificate (MDR)

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**No. G10 010066 0438 Rev. 04**

<b>Classification:</b>	Class IIb
<b>Device Group:</b>	K020101 - MONO- AND BIPOLAR SURGICAL INSTRUMENTS, SINGLE-USE
<b>Intended Purpose:</b>	<p>Depending on the design of the working end, the instruments are used for cutting, dissecting, grasping and suturing tissues, as well as for biopsies and/ or for thermal tissue treatment during minimal-invasive procedures.</p> <p>Bipolar forceps are used for hemostatic coagulation as well as grasping and dissecting of tissue in surgical procedures.</p> <p>The monopolar HF electrodes are combined with appropriate handles and generators, for coagulation and/ or dissecting (cutting) of tissue in endoscopic surgery.</p> <p>The single-use electrode handle with fingertip keys (monopolar) is fitted with a fixed cable and a disposable knife electrode and is used in open surgical procedures. The single-use electrode handle with fingertip keys (monopolar) is used to conduct the HF current from the HF device to the operating site, to hold the required working electrode and to activate the cutting or coagulating current supplied by the HF device.</p>
<b>Classification:</b>	Class IIb
<b>Device Group:</b>	K020102 - ELECTROSURGERY PADS (NEUTRAL ELECTRODES) AND CABLES, SINGLE-USE
<b>Intended Purpose:</b>	The neutral electrodes are used in the monopolar HF technique, where they serve to pick up the HF current from the wider area of operation on the patient's body and conduct it back to the HF device.
<b>Classification:</b>	Class IIb
<b>Device Group:</b>	K020301 - RADIOFREQUENCY SURGERY INSTRUMENTS, SINGLE-USE
<b>Intended Purpose:</b>	Caiman Seal & Cut is a bipolar RF sealing system, which consists of the LEKTRAFUSE RF Generator and Caiman instruments. This system can be used for grasping, preparation, sealing and cutting of tissue during open and minimally invasive surgical procedures. Caiman Seal & Cut can be used on vessels and vessel bundles with diameters up to and including 7 mm as well as soft tissue in general surgery and also surgical specialties such as gynecology, urology and bariatric, colorectal and thoracic surgery.
<b>Classification:</b>	Class IIb
<b>Device Group:</b>	L180201 - OPEN ELECTROSURGERY SCISSORS, REUSABLE
<b>Intended Purpose:</b>	Bipolar scissors are used for cutting, dissecting and coagulating tissues in surgical operations.



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Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III  
(Class IIa and Class IIb Devices)

**No. G10 010066 0438 Rev. 04**

**Classification:** Class IIb  
**Device Group:** L180202 - ENDOSCOPIC ELECTROSURGERY SCISSORS, REUSABLE  
**Intended Purpose:** Depending on the design of the working end, the instruments are used for cutting, dissecting, grasping and suturing tissues, as well as for biopsies and/ or for thermal tissue treatment during minimal-invasive procedures.

**Classification:** Class IIb  
**Device Group:** L180301 - OPEN ELECTROSURGERY HANDPIECES, REUSABLE  
**Intended Purpose:** The reusable electrode handles (monopolar) are fitted with a fixed cable and used to conduct the required HF current from the HF device to the operating site, to hold the required working electrode and, if applicable, to activate the cutting or coagulating current from the HF device (handles with activation keys).

**Classification:** Class IIb  
**Device Group:** L180302 - ENDOSCOPIC ELECTROSURGERY HANDPIECES, REUSABLE  
**Intended Purpose:** Depending on the design of the working end, the instruments are used for cutting, dissecting, grasping and suturing tissues, as well as for biopsies and/ or for thermal tissue treatment during minimal-invasive procedures.

The monopolar electrodes are high-quality products used for monopolar cutting, coagulating and dissecting in HF surgery.

**Classification:** Class IIb  
**Device Group:** L180401 - OPEN ELECTROSURGERY FORCEPS, REUSABLE  
**Intended Purpose:** Bipolar forceps are used for hemostatic coagulation as well as grasping and dissecting of tissue in surgical procedures.

These Aesculap instruments are used in general surgery. Depending on the design of the working ends, they are used for cutting, preparing, holding and/or monopolar coagulation.

**Classification:** Class IIb  
**Device Group:** L180402 - ENDOSCOPIC ELECTROSURGERY FORCEPS, REUSABLE  
**Intended Purpose:** Depending on the design of the working end, the instruments are used for cutting, dissecting, grasping and suturing tissues, as well as for biopsies and/ or for thermal tissue treatment during minimal-invasive procedures.





## EU Quality Management System Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III  
(Class IIa and Class IIb Devices)

**No. G10 010066 0438 Rev. 04**

**Classification:** Class IIb  
**Device Group:** L180601 - OPEN ELECTROSURGERY ELECTRODES, REUSABLE  
**Intended Purpose:** The monopolar HF electrodes are combined with appropriate handles and generators, for coagulation and/ or dissecting (cutting) of tissue in open surgery.

**Classification:** Class IIb  
**Device Group:** L180602 - ENDOSCOPIC ELECTROSURGERY ELECTRODES, REUSABLE  
**Intended Purpose:** The monopolar HF electrodes are combined with appropriate handles and generators, for coagulation and/ or dissecting (cutting) of tissue in endoscopic surgery.

**Classification:** Class IIa  
**Device Group:** Q019001 - SALIVA ASPIRATORS AND SALIVA ABSORBENTS  
**Intended Purpose:** -

**Classification:** Class IIa  
**Device Group:** T030199 - COVERS, INSTRUMENTS AND EQUIPMENT - OTHER  
**Intended Purpose:** -

**Classification:** Class IIa  
**Device Group:** V010101 - SCALPELS WITH SAFETY SYSTEMS, SINGLE-USE  
**Intended Purpose:** -

**Classification:** Class IIa  
**Device Group:** V010302 - BLADES WITHOUT SAFETY SYSTEMS, SINGLE-USE  
- NOT INCLUDED IN OTHER CLASSES  
**Intended Purpose:** -

**Classification:** Class IIa  
**Device Group:** V0199 - CUTTING DEVICES, SINGLE-USE - OTHER  
**Intended Purpose:** -

**Classification:** Class IIa  
**Device Group:** Z120103 - DERMOTOMY EQUIPMENT  
**Intended Purpose:** -



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**No. G10 010066 0438 Rev. 04**

**Classification:** Class IIb  
**Device Group:** Z120109 - ELECTROSURGICAL INSTRUMENTS  
**Intended Purpose:** The foot switch is used for activating compatible devices for HF surgery.

The bipolar HF generator is used for coagulation with bipolar instruments.

The HF generator is used for sealing and cutting of vessels with compatible seal and cut instruments.

**Classification:** Class IIa  
**Device Group:** Z120190 - VARIOUS INSTRUMENTS FOR GENERAL AND MULTIDISCIPLINARY SURGERY  
**Intended Purpose:** -

**Classification:** Class IIa  
**Device Group:** Z120190 - VARIOUS INSTRUMENTS FOR GENERAL AND MULTIDISCIPLINARY SURGERY  
**Intended Purpose:** -

**Classification:** Class IIa  
**Device Group:** Z120190 - VARIOUS INSTRUMENTS FOR GENERAL AND MULTIDISCIPLINARY SURGERY  
**Intended Purpose:** -

**Classification:** Class IIa  
**Device Group:** Z120114 - SURGICAL NAVIGATION INSTRUMENTS  
**Intended Purpose:** -

**Classification:** Class IIa  
**Device Group:** Z120114 - SURGICAL NAVIGATION INSTRUMENTS  
**Intended Purpose:** -

**Classification:** Class IIa  
**Device Group:** Z12011482 - SURGICAL NAVIGATION INSTRUMENTS - SOFTWARE ACCESSORIES  
**Intended Purpose:** -





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### No. G10 010066 0438 Rev. 04

<b>Classification:</b>	Class IIa
<b>Device Group:</b>	Z120204 - INSTRUMENTS FOR THE ACQUISITION AND MANAGEMENT OF ENDOSCOPIC AND MINIMALLY INVASIVE SURGERY IMAGES
<b>Intended Purpose:</b>	-
<b>Classification:</b>	Class IIa
<b>Device Group:</b>	Z120290 - VARIOUS INSTRUMENTS FOR ENDOSCOPY AND MINI-INVASIVE SURGERY
<b>Intended Purpose:</b>	-
<b>Classification:</b>	Class IIa
<b>Device Group:</b>	Z120290 - VARIOUS INSTRUMENTS FOR ENDOSCOPY AND MINI-INVASIVE SURGERY
<b>Intended Purpose:</b>	-
<b>Classification:</b>	Class IIa
<b>Device Group:</b>	Z120590 - VARIOUS INSTRUMENTS FOR CARDIOLOGY AND CARDIAC SURGERY
<b>Intended Purpose:</b>	-
<b>Classification:</b>	Class IIa
<b>Device Group:</b>	Z121305 - MOTORISED ORTHOPAEDIC SURGERY SYSTEM INSTRUMENTS
<b>Intended Purpose:</b>	-
<b>Classification:</b>	Class IIa
<b>Device Group:</b>	Z121305 - MOTORISED ORTHOPAEDIC SURGERY SYSTEM INSTRUMENTS
<b>Intended Purpose:</b>	-
<b>Classification:</b>	Class IIa
<b>Device Group:</b>	Z121009 - INSTRUMENTS FOR MOTORISED NEUROSURGERY SYSTEMS
<b>Intended Purpose:</b>	-
<b>Classification:</b>	Class IIa
<b>Device Group:</b>	Z121009 - INSTRUMENTS FOR MOTORISED NEUROSURGERY SYSTEMS
<b>Intended Purpose:</b>	-



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**Classification:** Class IIa  
**Device Group:** Z121009 - INSTRUMENTS FOR MOTORISED NEUROSURGERY SYSTEMS  
**Intended Purpose:** -

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

### Revision History:

Rev.	Dated	Report	Description
00	2020-07-10	713175266	-
01	2021-12-09	713203407 / 713203404 / 713203403 / 713203400 / 713203397 / 713203393 / 713203388 / 713205439 / 713229575	-
02	2022-11-08	713203406 / 713205438 / 713218837 / 713218822	-
03	2022-11-17	713203406 / 713205438 / 713218837 / 713218822	-
04	2023-11-07	713218567 / 713218653 / 713218808 / 713230390 / 713303316	Supplemented: Device(s)/group of device(s) added