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Product Service

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

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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(Class IIa and Class IIb Devices)

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:	-

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No. G10 010066 0438 Rev. 04

Classification:	Class IIa
Device Group:	L110501 - VERTEBRAL SURGERY SPREADERS AND RETRACTORS, REUSABLE
Intended Purpose:	-

Classification:	Class IIa
Device Group:	L110503 - CRANIAL SURGERY SPREADERS AND RETRACTORS, REUSABLE
Intended Purpose:	-

Classification:	Class IIa
Device Group:	L149003 - ENT RETRACTORS, REUSABLE
Intended Purpose:	-

Classification:	Class IIa
Device Group:	L031201 - THORACIC TROCAR, REUSABLE
Intended Purpose:	-

Classification:	Class IIa
Device Group:	L031202 - ABDOMINAL TROCAR, REUSABLE
Intended Purpose:	-

Classification:	Class IIa
Device Group:	L031280 - SURGICAL TROCAR, REUSABLE - ACCESSORIES
Intended Purpose:	-

Classification:	Class IIa
Device Group:	A019001 - BLUNT NEEDLES
Intended Purpose:	-

Classification:	Class IIa
Device Group:	A070199 - ADAPTERS AND CONNECTORS - OTHER
Intended Purpose:	-

Classification:	Class IIa
Device Group:	C019019 - VESSEL STRIPPER SYSTEMS
Intended Purpose:	-

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No. G10 010066 0438 Rev. 04

Classification:	Class IIa
Device Group:	G020401 - HAEMORRHOID LIGATURE SETS
Intended Purpose:	-

Classification:	Class IIa
Device Group:	H030102 - SINGULAR CLIPS FOR OPEN SURGERY
Intended Purpose:	-

Classification:	Class IIa
Device Group:	H030201 - MULTIPLE CLIP APPLIERS FOR VIDEOSURGERY
Intended Purpose:	-

Classification:	Class IIa
Device Group:	H030201 - MULTIPLE CLIP APPLIERS FOR VIDEOSURGERY
Intended Purpose:	-

Classification:	Class IIa
Device Group:	K010101 - TROCAR, SINGLE-USE
Intended Purpose:	-

Classification:	Class IIa
Device Group:	K010201 - MINIMALLY INVASIVE SURGERY SURGICAL INSTRUMENTS, SINGLE-USE
Intended Purpose:	-

Classification:	Class IIa
Device Group:	K010201 - MINIMALLY INVASIVE SURGERY SURGICAL INSTRUMENTS, SINGLE-USE
Intended Purpose:	-

Classification:	Class IIa
Device Group:	K0104 - VERESS NEEDLES
Intended Purpose:	-

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No. G10 010066 0438 Rev. 04

Classification:	Class IIb
Device Group:	K020101 - MONO- AND BIPOLAR SURGICAL INSTRUMENTS, SINGLE-USE
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. Bipolar forceps are used for hemostatic coagulation as well as grasping and dissecting of tissue in surgical procedures. The monopolar HF electrodes are combined with appropriate handles and generators, for coagulation and/ or dissecting (cutting) of tissue in endoscopic surgery. 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.

Classification:	Class IIb
Device Group:	K020102 - ELECTROSURGERY PADS (NEUTRAL ELECTRODES) AND CABLES, SINGLE-USE
Intended Purpose:	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.

Classification:	Class IIb
Device Group:	K020301 - RADIOFREQUENCY SURGERY INSTRUMENTS, SINGLE-USE
Intended Purpose:	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.

Classification:	Class IIb
Device Group:	L180201 - OPEN ELECTROSURGERY SCISSORS, REUSABLE
Intended Purpose:	Bipolar scissors are used for cutting, dissecting and coagulating tissues in surgical operations.

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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.

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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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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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Classification:	Class IIa
Device Group:	Z120204 - INSTRUMENTS FOR THE ACQUISITION AND MANAGEMENT OF ENDOSCOPIC AND MINIMALLY INVASIVE SURGERY IMAGES
Intended Purpose:	-

Classification:	Class IIa
Device Group:	Z120290 - VARIOUS INSTRUMENTS FOR ENDOSCOPY AND MINI-INVASIVE SURGERY
Intended Purpose:	-

Classification:	Class IIa
Device Group:	Z120290 - VARIOUS INSTRUMENTS FOR ENDOSCOPY AND MINI-INVASIVE SURGERY
Intended Purpose:	-

Classification:	Class IIa
Device Group:	Z120590 - VARIOUS INSTRUMENTS FOR CARDIOLOGY AND CARDIAC SURGERY
Intended Purpose:	-

Classification:	Class IIa
Device Group:	Z121305 - MOTORISED ORTHOPAEDIC SURGERY SYSTEM INSTRUMENTS
Intended Purpose:	-

Classification:	Class IIa
Device Group:	Z121305 - MOTORISED ORTHOPAEDIC SURGERY SYSTEM INSTRUMENTS
Intended Purpose:	-

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

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

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No. G10 010066 0438 Rev. 04

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

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