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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 IIa and Class IIb Devices)

No. G10 031564 0017 Rev. 01

Manufacturer:

Ulrich AG
Mövenstraße 12
9015 St. Gallen
SWITZERLAND

SRN Manufacturer - Not available at issuance date

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 031564 0017 Rev. 01

Report No.: 713239169_CN

Preceding Certificate No.: G10 031564 0017 Rev. 00

Valid from: 2023-05-02
Valid until: 2025-07-31

Date of Initial Issuance: 2021-02-01

Christoph Dicks
Head of Certification/Notified Body

Issue date: 2023-05-02

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123
TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

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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:	L080602 - THORACIC SURGERY SPREADERS, REUSABLE
Intended Purpose:	-

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 IIb
Device Group:	L180401 - OPEN ELECTROSURGERY FORCEPS, REUSABLE
Intended Purpose:	Monopolar reusable forceps are designed to grasp, manipulate and coagulate different tissues. These instruments do not have a specific indication.

Classification:	Class IIb
Device Group:	L180401 - OPEN ELECTROSURGERY FORCEPS, REUSABLE
Intended Purpose:	Bipolar reusable forceps are designed to grasp and coagulate different tissues. These instruments do not have a specific indication.

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

Revision History:

Rev.	Dated	Report	Description
00	2021-02-01	713179391	-
01	2023-05-02	713239169_CN	Supplemented: Device(s)/group of device(s) added

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