





**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

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

documentation for devices selected on a representative basis.

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

Date of Initial Issuance: 2021-02-01

Christoph Dicks

Issue date: 2023-05-02 Head of Certification/Notified Body







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### No. G10 031564 0017 Rev. 01

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

L180401 - OPEN ELECTROSURGERY FORCEPS, REUSABLE **Device Group:** 

**Intended Purpose:** Monopolar reusable forceps are designed to grasp, manipulate

and coagulate different tissues. These instruments do not have a

specific indication.

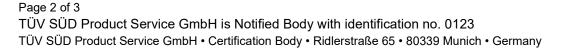
Classification: Class IIb

L180401 - OPEN ELECTROSURGERY FORCEPS, REUSABLE **Device Group: 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
00	2021-02-01	713179391
01	2023-05-02	713239169_CN

#### Description

Supplemented: Device(s)/group of device(s) added