



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 011099 0511 Rev. 00

Manufacturer:

ulrich GmbH & Co. KG

Buchbrunnenweg 12
89081 Ulm
GERMANY

SRN Manufacturer - DE-MF-000006411

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 011099 0511 Rev. 00](http://www.tuvsud.com/ps-cert?q=cert:G10_011099_0511_Rev.00)

Report No.: 713315823

Valid from: 2023-12-21

Valid until: 2028-12-20

Christoph Dicks
Head of Certification/Notified Body

Issue date: 2023-12-21



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Classification: Class IIb
Device Group: Z110390 - VARIOUS INSTRUMENTS FOR RADIODIAGNOSTICS AND INTERVENTIONAL PROCEDURES
Intended Purpose: Contrast medium injector for injection of liquids and drugs for diagnostic examinations

Classification: Class IIb
Device Group: P090703 - IMPLANTABLE VERTEBRAL STABILISATION OR FIXATION SYSTEMS
Intended Purpose: System, intended to be used for fixation, stabilisation or correction of spinal segments in craniocervical, cervical or cervicothoracic spine

Classification: Class IIb
Device Group: P090703 - IMPLANTABLE VERTEBRAL STABILISATION OR FIXATION SYSTEMS
Intended Purpose: System, intended to be used for fixation, stabilisation or correction of spinal segments in thoracic, lumbar or sacral spine or ilium

Classification: Class IIa
Device Group: L091001 - INSTRUMENTS FOR INSERTION AND EXTRACTION OF MATERIALS FOR OSTEOSYNTHESIS, REUSABLE
Intended Purpose: -

Classification: Class IIa
Device Group: P091399 - ORTHOPAEDIC IMPLANT INSTRUMENTS, SINGLE-USE - OTHER
Intended Purpose: -

Classification: Class IIa
Device Group: A03010105 - INFUSION PUMP CONTROLLERS
Intended Purpose: -

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

Revision History:

Rev.	Dated	Report	Description
00	2023-12-21	713315823	Initial issuance