

EU Quality Management System Certificate

Certificate no.
20379GB448240528

Final Assessment Report no.
20379AU01F

Effective date
2024-05-28

Expiry date
2028-04-20

This is to certify that the quality system of
Ulrich GmbH & Co. KG
Buchbrunnenweg 12, 89081 Ulm, Germany
SRN: DE-MF-000006411

For design, production, and final product inspection/testing of
Medical devices/groups of medical devices listed on the following pages

Has been assessed and found to comply with respect to
**The conformity assessment procedure described in Annex IX,
Chapters I and III of Regulation (EU) 2017/745 on Medical Devices**

Any applicable limitations for certain medical devices are included in the following list or recorded
in the final assessment report. This certification is subject to surveillance by DNV MEDCERT.

Place and date
Hamburg, 2024-05-28

For the issuing office
DNV MEDCERT GmbH – Notified Body 0482
Pilatuspool 2, 20355 Hamburg, Germany



Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
www.zlg.de
BS-MDR-096

Marcus Harder
Director Certification Body

The certificate is only valid when provided entirely with
all of its pages. To verify the validity of this certificate,
contact Medcert-Info@dnv.com



Certificate no.: 20379GB448240528
Place and date: Hamburg, 2024-05-28

Sites covered by this certificate

Ulrich GmbH & Co. KG, Buchbrunnenweg 12, 89081 Ulm, Germany
Ulrich GmbH & Co. KG, Logistikzentrum, Mergelgrube 1, 89081 Ulm, Germany

Products covered by this certificate

Class I medical devices

For class I medical devices that are reusable surgical instruments (class Ir), the audit of the quality management system was limited to the aspects relating to the reuse of the device, in particular cleaning, disinfection, sterilisation, maintenance and functional testing, and the related instructions for use.

| Category | Class | Medical devices/groups of medical devices |
|----------|-------|---|
| MDN 1208 | Ir | Non-active non-implantable instruments |

Class IIa medical devices

| Category | EMDN code | Medical devices/groups of medical devices |
|----------|-----------|---|
| MDN 1208 | P091399 | Orthopaedic implant instruments, single-use - other |

Class III medical devices

For placing on the market of class III medical devices covered by this certificate, an additional EU Technical Documentation Assessment Certificate according to Annex IX Chapter II of Regulation (EU) 2017/745 is required, which also contains the exact determination of medical devices covered by certification.

| Category | Medical devices/groups of medical devices |
|----------|--|
| MDN 1102 | Non-active osteo- and orthopaedic implants |