

CERTIFICATE

Number: 2278620

The management system of the organization(s) and locations mentioned on the addendum belonging to:

Joline GmbH & Co. KG

Neue Rottenburger Str. 50
72379 Hechingen
Germany

Manufacturer Facility Identifier F006927

Conforms with the following standard and regulatory requirements:

ISO 13485:2016

Brazil: RDC ANVISA n. 665/2022, 551/2021 and 67/2009
Canada: Medical Devices Regulations - Part 1- SOR 98/282
Japan: MHLW Ministerial Ordinance 169, Article 4 to Article 68 and PMD Act
United States: 21 CFR 803, 21 CFR 806, 21 CFR 807 - Subparts A to D, 21 CFR 820 and 21 CFR 821

Scope:

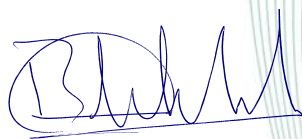
Development, manufacturing, storage and distribution of:

- catheter systems and instruments for intensive care and nephrology
- catheter systems and instruments for orthopaedics
- instruments for cardiology

Development and manufacturing of stents

Certificate expiry date: 2026-12-01
Certificate effective date: 2024-05-30
Certified since: 2023-12-18

This certificate is valid for the organization(s) and/or locations mentioned on the addendum.
DEKRA Certification B.V.



B.T.M. Holtus
Managing Director



J.M. McKenzie
Certification Manager

© Integral publication of this certificate and adjoining reports is allowed

The validation of the validity of this certificate can be checked through DEKRA's website using the following link:
<https://www.dekra-checkme.com/org>

DEKRA Certification B.V. is recognized under the Medical Devices Single Audit Program.



ADDENDUM

To certificate: 2278620

The management system of the organization(s) and/or location(s) of:

Joline GmbH & Co. KG

Neue Rottenburger Str. 50
72379 Hechingen
Germany

Certified organization(s) and/or locations:

Different scope

Joline GmbH & Co. KG
Lotzenäcker 3
72379 Hechingen
Germany
Facility Identifier F006927

Development and manufacturing of stents

Joline GmbH & Co. KG
Neue Rottenburger Str. 48
72379 Hechingen
Germany
Facility Identifier F006927

Storage and distribution of
- catheter systems and instruments for intensive care and nephrology
- catheter systems and instruments for orthopedics
- Instruments for cardiology

Addendum expiry date: 2026-12-01

Addendum effective date: 2024-05-30