

# 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

Conforms with the following standard and regulatory requirements:

## ISO 13485:2016

Brazil: RDC ANVISA n. 665/2022, 551/2021 and 67/2009

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

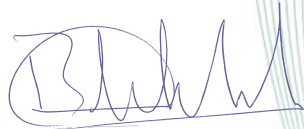
Certificate expiry date: 2026-12-01

Certificate effective date: 2023-12-18

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-product-safety.com/en/certified-organizations>

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  
Neue Rottenburger Str. 48  
72379 Hechingen  
Germany

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

Joline GmbH & Co. KG  
Lotzenäcker 3  
72379 Hechingen  
Germany

Development and manufacturing of stents

Addendum expiry date: 2026-12-01  
Addendum effective date: 2023-12-18