

# CERTIFICATE



## EN ISO 13485:2016 + AC:2018 + A11:2021

DEKRA Certification GmbH hereby certifies that the organization

**Joline GmbH & Co. KG**

### Scope of certification:

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

### Certified location:

Neue Rottenburger Str. 50, 72379 Hechingen, Germany  
(further locations see annex)

has established and maintains a quality management system according to the above mentioned standard.  
The conformity was adduced with audit report no. 50565-R4-00.

Certificate registration no.: 50565-21-00\_EN

Validity of previous certificate: 2023-11-29

Certificate valid from: 2023-11-30

Certificate valid to: 2026-11-29

Karin Leicht  
DEKRA Certification GmbH, Stuttgart, 2023-11-28



Deutsche  
Akkreditierungsstelle  
D-ZM-16029-08-00



# Annex to the Certificate No. 50565-21-00

valid from 2023-11-30 to 2026-11-29

The following locations/companies belong to the certificate above:

	Headquarters	Certified location	Scope of certification
	Joline GmbH & Co. KG	Neue Rottenburger Straße 50 72379 Hechingen Germany	see page 1
	at the following locations/at the companies at the following locations		Scopes of certification
1.		Neue Rottenburger Straße 48 72379 Hechingen Germany	Storage and distribution of <ul style="list-style-type: none"><li>• catheter systems and instruments for intensive care and nephrology</li><li>• catheter systems and instruments for orthopaedics</li><li>• instruments for cardiology</li></ul>
2.		Lotzenäcker 3 72379 Hechingen Germany	Development and manufacturing of stents



Karin Leicht

DEKRA Certification GmbH, Stuttgart, 2023-11-28





# EC CERTIFICATE

## for the Quality Assurance System



**according the Directive 93/42/EEC,  
Annex II excluding section (4)**

As a Notified Body of the European Union, DEKRA Certification GmbH certifies, that the company

**Joline GmbH & Co. KG**

Neue Rottenburger Straße 50, 72379 Hechingen, Germany

applies a quality assurance system according to the Directive 93/42/EEC Annex II for the medical devices listed in the annex. The approval is based on the result of the re-certification audit report no. 50565-Z5-00, the decision dated 2018-10-04 and is only valid in connection with the successful performance of the annual surveillance audits.

This certificate is valid from 2018-11-30 to 2023-11-29

Registration No.: 50565-16-06



Ruth Delbeck-Bayer  
DEKRA Certification GmbH Stuttgart; 2018-10-04  
Notified Body ID-number: 0124



Benannt durch/Designated by  
Zentralstelle der Länder  
für Gesundheitsschutz  
bei Arzneimitteln und  
Medizinprodukten  
[www.zlg.de](http://www.zlg.de)  
**ZLG-BS-295.10.02**

DEKRA Certification GmbH \* Handwerkstraße 15 \* D-70565 Stuttgart \* [www.dekra-certification.de](http://www.dekra-certification.de)



# Annex to the EC Certificate No. 50565-16-06

Valid from 2018-11-30 to 2023-11-29

Revision status of the annex: 2 dated 2020-12-22

Devices/device categories included in the certificate:

## Class II a:

### MD 0102

- Dialysis Catheter ST
  - Kits
  - Catheter

### MD 0106

- Kyphoplasty Systems ALLEVO
  - Kits
  - Individual Instruments
- Dialysis Accessories
  - Introducer Needle
  - Guide Wire
  - Dilator
  - Trocar
  - Connector LT

## Class III:

### MD 0203

- Dialysis Catheter PU-LT
  - Kits
  - Catheter
- Dialysis Catheter Silicone LT
  - Kits
  - Catheter

For the placing on the market of class III devices covered by this certificate an EC design-examination certificate according to directive 93/42/EEC annex II (4) is required.



Ruth Delbeck-Bayer  
DEKRA Certification GmbH, Stuttgart, 2020-12-22  
Notified Body ID-number: 0124

DEKRA Certification GmbH \* Handwerkstraße 15 \* D-70565 Stuttgart \* [www.dekra.de/audits](http://www.dekra.de/audits)



# EC CERTIFICATE

## for the Quality Assurance System



### according the Directive 93/42/EEC, Annex V

As a Notified Body of the European Union, DEKRA Certification GmbH certifies, that the company

**Joline GmbH & Co. KG**

Neue Rottenburger Straße 50, 72379 Hechingen, Germany

applies a quality assurance system according to the Directive 93/42/EEC Annex V for the medical devices listed in the annex. The approval is based on the result of the re-certification audit report no. 50565-Z5-00, the decision dated 2018-10-04 and is only valid in connection with the successful performance of the annual surveillance audits.

This certificate is valid from 2018-11-30 to 2023-11-29

Registration No.: 50565-17-05

*Ruth Delbeck-Bayer*



Ruth Delbeck-Bayer  
DEKRA Certification GmbH Stuttgart; 2018-10-04  
Notified Body ID-number: 0124

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**ZLG-BS-295.10.02**



# Annex to the EC Certificate No. 50565-17-05

Valid from 2018-11-30 to 2023-11-29

Revision status of the annex: 0 dated 2018-11-30

Devices/device categories included in the certificate:

## Class I s:


For the products listed below, review of the Quality Assurance System refers exclusively to aspects of manufacture concerned with securing and maintaining sterile conditions.

MD 0101

- Miniclamp

MD 0106

- Mixer



Ruth Delbeck-Bayer  
DEKRA Certification GmbH, Stuttgart, 2018-10-04  
Notified Body ID-number: 0124

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