

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">• catheter systems and instruments for intensive care and nephrology• catheter systems and instruments for orthopaedics• instruments for cardiology
2.		Lotzenäcker 3 72379 Hechingen Germany	Development and manufacturing of stents



K. Leicht

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
ZLG-BS-295.10.02

DEKRA Certification GmbH * Handwerkstraße 15 * D-70565 Stuttgart * 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

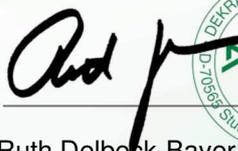
- Kyphoplasty Systems ALLEVO
- Kits
- Individual Instruments
- Dialysis Accessories
- Introducer Needle
- Guide Wire
- Dilator
- Trocar
- Connector LT

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

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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



A handwritten signature in black ink, appearing to read 'Ruth Delbeck-Bayer', written over a horizontal line.



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

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