

# 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: 1 dated 2019-05-20

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

MD 0106

- Biopsy Forceps KNIPSA

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, 2019-05-20  
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", is written over a horizontal line.



Ruth Delbeck-Bayer  
DEKRA Certification GmbH, Stuttgart, 2018-10-04  
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