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

DEKRA Certification GmbH • Stuttgart, Handwerkstraße 15 • D-70565

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

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

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 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
- Stone Extraction Catheter

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.

DEKRA Certification GmbH • D-70565 Stuttgart, Handwerkstraße 15 • DEKRA Certification

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

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

DEKRA Certification GmbH • DEKRA Certification • D-70565 Stuttgart, Handwerkstraße 15

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-295.10.02

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

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

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

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