EU Certificate

for the assessment of the quality management system

according to Medical Device Regulation (EU) 2017/745 Annex IX Chapter I+III

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

Joline GmbH & Co. KG

Single Registration Number (SRN): DE-MF-000005494
Neue Rottenburger Straße 50, 72379 Hechingen, Germany

applies a quality management system according to Annex IX Chapter I+III of the Medical Device Regulation (EU) 2017/745 for the medical devices listed in the annex. This certificate is based on the assessments listed in CNo50565-00.

EU Certificate no.: 50565-60-01

Certificate valid from: 2023-06-30
Certificate valid to: 2025-11-29

Previous certificate no. 50565-60-00, valid from 2020-11-30 to 2023-06-29
Changes to previous certificate: Addition SRN-No., Reference CNo

DEKRA Certification GmbH • D-70565 Stuttgart, Handwerkstraße 15

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-MDR-092

Karin Leicht
DEKRA Certification GmbH, Stuttgart, 2023-06-30
Notified Body ID number: 0124

Annex to the EU Certificate no. 50565-60-01

valid from 2023-06-30 to 2025-11-29

Revision status of the annex: 1 dated 2023-09-20

Following devices/device categories are included in this certificate:

Class Is

For the devices listed below, the review of the quality management system refers exclusively to the aspects relating to establishing, securing and maintaining sterile conditions.

- MDN 1202 (Non-active non-implantable devices for administration, channelling and removal of substances, including devices for dialysis)
    - Mini clamp, Basis-UDI-DI: 42502039109901464
- MDN 1208 (Non-active non-implantable instruments)
    - Mixer, Basis-UDI-DI: 42502039 2011000 ZP

Class III

- MDN 1208 (Non-active non-implantable instruments)
    - Biopsy Forceps Knipsa, Basis-UDI-DI: 42502039 8020000 54

For the initial placing on the market of class III devices covered by this certificate, an EC EU technical documentation assessment certificate according to Regulation (EU) 2017/745 Annex IX Chapter II is required.

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Karin Leicht
DEKRA Certification GmbH, Stuttgart, 2023-09-20
Notified Body ID-number: 0124