

Manufacturer's Declaration

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|---|---|
| Manufacturer name | Joline GmbH & Co. KG |
| Manufacturer address and contact details | Neue Rottenburger Str. 50 72379 Hechingen Germany |
| Single Registration Number (SRN) | DE-MF-000005494 |

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|--|----------------------------------|
| Notified body name | DEKRA Certification GmbH |
| Notified body number | 0124 |
| Directive Certificate number(s) to which this confirmation is made | see attached schedule of devices |
| Original expiry date as indicated on the Directive Certificate prior to the extension of the validity | see attached schedule of devices |
| End date of extended validity/transition period | see attached schedule of devices |

In relation to Regulation (EU) 2023/607 amending Regulation (EU) 2017/745 (MDR) as regards the transitional provisions for certain medical devices, in particular with respect to

- the validity of certificates issued under Council Directive 93/42/EEC on Medical Devices (MDD) (Directive Certificates) *and/or*
- the compliance of the devices and us as their manufacturer with the conditions for the continued placing on the market and putting into service

we, as the manufacturer, declare under our sole responsibility for the affected listed **Directive Certificates** (see attached schedule), the **listed device(s) in the attached schedule of devices** that we as their manufacturer are in compliance with the conditions listed in Article 120(3c) of the MDR for continued placing on the market and putting into service, namely by fulfilling the following conditions:

➤ **Directive Certificate(s)** as listed above or in the attached schedule

Directive Certificates covering the listed devices were issued after 25 May 2017, were valid on 26 May 2021 and have not been withdrawn afterwards. They expire *after* 20 March 2023:

We have made formal applications to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment to our notified body no later than 26 May 2024 for the devices listed in the attached schedule. Signed written agreements with our notified body will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.

➤ **Quality Management System (QMS)**

A QMS in accordance with Article 10(9) MDR is in place.

➤ **Device(s) as listed in the attached schedule**

- The device(s) continue to comply with the MDD.
- There are no significant changes in the design and intended purpose.
- The device(s) do not present an unacceptable risk to health or safety of patients, users or other persons, or to other aspects of the protection of public health.

Signed for and on behalf of the manufacturer:

Hechingen, 2023-11-06

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i.A. Dr. Marian Wenzel
Director QA/RA, Person Responsible for Regulatory Compliance
Joline GmbH & Co. KG

Joline®

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Schedule of Devices

The Manufacturer's Declaration above is valid for the following devices:

| Identification of the device(s) (e.g., device name, family/group name device model or catalogue number) | Directive Certificate number(s) to which this confirmation is made | Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity | Notified Body name and number that issued the Directive Certificate | Notified Body name and number where the MDR application was lodged/contract signed | End date of extended validity / transition period | Substitute Device(s) |
|---|--|---|---|--|---|----------------------|
| Kyphoplasty Systems ALLEVO <ul style="list-style-type: none"> • Kits • Individual Instruments | 50565-16-06 | <u>2023-11-29</u> | DEKRA Certification GmbH, ID 0124 | DEKRA Certification GmbH, ID 0124 | <u>2028-12-31</u> | N/A |
| Dialysis Catheter ST <ul style="list-style-type: none"> • Kits • Catheter | 50565-16-06 | <u>2023-11-29</u> | DEKRA Certification GmbH, ID 0124 | DEKRA Certification GmbH, ID 0124 | <u>2028-12-31</u> | N/A |
| Dialysis Catheter PU-LT <ul style="list-style-type: none"> • Kits • Catheter | 50565-16-06 | <u>2023-11-29</u> | DEKRA Certification GmbH, ID 0124 | DEKRA Certification GmbH, ID 0124 | <u>2027-12-31</u> | N/A |
| Dialysis Catheter Silicone LT <ul style="list-style-type: none"> • Kits • Catheter | 50565-16-06 | <u>2023-11-29</u> | DEKRA Certification GmbH, ID 0124 | DEKRA Certification GmbH, ID 0124 | <u>2027-12-31</u> | N/A |
| Dialysis Accessories: <ul style="list-style-type: none"> • Introducer needle | 50565-16-06 | <u>2023-11-29</u> | DEKRA Certification GmbH, ID 0124 | DEKRA Certification GmbH, ID 0124 | <u>2028-12-31</u> | N/A |
| Dialysis Accessories: <ul style="list-style-type: none"> • Dilator | 50565-16-06 | <u>2023-11-29</u> | DEKRA Certification GmbH, ID 0124 | DEKRA Certification GmbH, ID 0124 | <u>2028-12-31</u> | N/A |
| Dialysis Accessories: <ul style="list-style-type: none"> • Connector LT | 50565-16-06 | <u>2023-11-29</u> | DEKRA Certification GmbH, ID 0124 | DEKRA Certification GmbH, ID 0124 | <u>2028-12-31</u> | N/A |
| Miniclamp | 50565-17-05 | <u>2023-11-29</u> | DEKRA Certification GmbH, ID 0124 | DEKRA Certification GmbH, ID 0124 | <u>2028-12-31</u> | N/A |
| Mixer | 50565-17-05 | <u>2023-11-29</u> | DEKRA Certification GmbH, ID 0124 | DEKRA Certification GmbH, ID 0124 | <u>2028-12-31</u> | N/A |