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Nur zur elektronischen Verbreitung

# EU Quality Management System Certificate

We hereby certify the company

**Kohler Medizintechnik GmbH**
**Bodenseeallee 14-16**
**78333 Stockach**
**Germany**

the introduction and application of a quality management system in accordance with Annex IX, Chapter I and III of Regulation (EU) 2017/745 for conformity assessment.

An audit by mdc has proven that this quality management system meets the following requirements:

## Annex IX – Chapter I (Quality Management System)

of Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices.

Surveillance is carried out in accordance with Annex IX, Section 3 of Regulation (EU) 2017/745.

This certificate from mdc medical device certification GmbH (Notified Body 0483) consists of 2 pages. Details about the devices covered as well as further information and conditions are contained on the following pages.

| | | | |
|---|---|---|---|
| Valid from | 2026-01-30 | Registration No. | D1067500018 |
| Valid until | 2029-05-15 | Report No. | P25-00861-340786 |

Stuttgart, 2026-01-30

Notified Body

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-MDR-098

## Devices:

Ablating reusable surgical instruments

Risk class: I (reusable)

Ablating and Severing reusable surgical instruments

Risk class: I (reusable)

Halting reusable surgical instruments

Risk class: I (reusable)

Contributing reusable surgical instruments

Risk class: I (reusable)

Retaining reusable surgical instruments

Risk class: I (reusable)

Cutting reusable surgical instruments

Risk class: I (reusable)

Investigating reusable surgical instruments

Risk class: I (reusable)

## Notes:

In the case of class I devices that are reusable surgical instruments the involvement of mdc is limited to the aspects relating to the reuse of the device, in particular cleaning, disinfection, sterilization, maintenance and functional testing as well as the related instructions for use.