

# EU Quality Management System Certificate

We hereby certify the company

**Tekno-Medical Optik-Chirurgie GmbH**  
**Sattlerstraße 11**  
**78532 Tuttlingen**  
**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 2024-10-17  
Valid until 2029-01-04

Registration No. D1043500089  
Report No. P24-00873-315131

Stuttgart, 2024-10-17



Notified Body



## Devices:

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Self-retaining Retractors

Risk class: IIa

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Access Instruments

Risk class: IIa

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Optics

Risk class: IIa

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Cannulas

Risk class: IIa

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Holding Instruments

Risk class: I (reusable)

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Cutting Instruments

Risk class: I (reusable)

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Spreading and widening Instruments

Risk class: I (reusable)

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## 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.