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	Registration No.	D1043500089
Valid until	2029-01-04	Report No.	P24-00873-315131

Stuttgart, 2024-10-17

Notified Body

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

Devices:

Self-retaining Retractors

Risk class: IIa

Access Instruments

Risk class: IIa

Optics

Risk class: IIa

Cannulas

Risk class: IIa

Holding Instruments

Risk class: I (reusable)

Cutting Instruments

Risk class: I (reusable)

Spreading and widening 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.