

EU Quality Management System Certificate

We hereby certify the company

ELCON Medical Instruments GmbH
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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 3 pages. Details about the devices covered as well as further information and conditions are contained on the following pages.

Valid from 2025-10-30
Valid until 2029-10-16

Registration No. D1068800007
Report No. P25-00252-325750

Stuttgart, 2025-10-30



Notified Body



Devices:

Cutting reusable surgical instruments, including cutting reusable surgical instruments for ophthalmology

Risk class: I (reusable)

Holding reusable surgical instruments, including holding reusable surgical instruments for ophthalmology

Risk class: I (reusable)

Rotating reusable surgical instruments

Risk class: I (reusable)

Exerting strength reusable surgical instruments

Risk class: I (reusable)

Examining reusable surgical instruments, including examining reusable surgical instruments for ophthalmology

Risk class: I (reusable)

Expanding reusable surgical instruments, including expanding reusable surgical instruments for ophthalmology

Risk class: I (reusable)

Introducing reusable surgical instruments

Risk class: I (reusable)

Puncturing reusable surgical instruments, including puncturing reusable surgical instruments for ophthalmology

Risk class: I (reusable)

Ablating reusable surgical instruments, including ablating reusable surgical instruments for ophthalmology

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.