

# EU Quality Management System Certificate

We hereby certify the company

**a1 medical GmbH**  
**Lessingstr. 50**  
**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 2026-04-26  
Valid until 2031-04-25

Registration No. D1479100006  
Report No. P25-00918-342036

Stuttgart, 2026-04-14



Notified Body



## Devices:

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surgical and microsurgical instruments for ophthalmology

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.

## The certificate is based on the previous certificate

D1479100002 (2021-04-26)

with the following changes to D1479100002:

Re-Certification with new term