

EU Quality Management System Certificate

Certificate no.
2073GB448241112

Final Assessment Report
2072AU24F

Effective date
2024-11-12

Expiry date
2027-07-26

This is to certify that the quality system of

Medicel AG

Dornierstrasse 11, 9423 Altenrhein, Switzerland

SRN: CH-MF-000016652

For design, production, and final product inspection/testing of
Medical devices/groups of medical devices listed on the following pages

Has been assessed and found to comply with respect to

The conformity assessment procedure described in Annex IX, Chapters I and III of Regulation (EU) 2017/745 on Medical Devices

Any applicable limitations for certain medical devices are included in the following list or recorded in the final assessment report. This certification is subject to surveillance by DNV MEDCERT.

Place and date
Hamburg, 2024-11-12

For the issuing office
DNV MEDCERT GmbH – Notified Body 0482
Pilatuspool 2, 20355 Hamburg, Germany



Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
www.zlfg.de

BS-MDR-096

The certificate is only valid when provided entirely with all of its pages. To verify the validity of this certificate, contact Medcert-Info@dnv.com


Anika Chil
Certification Body



Certificate no.: [2073GB448241112](#)
Place and date: [Hamburg, 2024-11-12](#)

Sites covered by this certificate

Medicel AG, Dornierstrasse 11, 9423 Altenrhein, Switzerland

Authorised representative

Rudolf Riester GmbH, Bruckstrasse 31, 72417 Jungingen, Germany
SRN: DE-AR-000015844





DNV

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Products covered by this certificate

Class IIa medical devices

Category	EMDN code	Medical devices/groups of medical devices
MDN 1206	Q0211	OPHTHALMIC SURGERY INSTRUMENTS, SINGLE-USE
MDA 0309	Q0206	PHACOEMULSIFICATION DEVICES
	Q0211	OPHTHALMIC SURGERY INSTRUMENTS, SINGLE-USE

