EU Quality Management Certificate

This is to certify that the company

SIE AG , Surgical Instrument Engineering

Allmendstrasse 11
2562 Port
Switzerland

SRN: CH-MF-000025018
SRN: CH-PR-000023323

has established, implemented and maintains a Quality Management System in accordance with

Annex IX, Chapter I and III of the Regulation (EU) 2017/745

Conformity Assessment based on a Quality Management System and on Assessment of Technical Documentation

for the device categories and products listed in the Annex of this certificate.

The conformity of the Quality Management System has been verified in an audit and is subject to regular surveillance in accordance with Annex IX, Chapter 1, Section 3.
Limitations to this certificate are listed in the Annex.

Devices listed in the Annex may bear the CE marking with the identification number of the Notified Body (0297).

For placing of devices of class III and devices class IIb implantable according to Article 52(4) subparagraph 2 listed in the Annex on the market, an additional certificate according to Annex IX, Chapter II is required.

Certificate registration no.	333427 MDR2017Q
Certificate ID	1000167723
Effective date	2024-03-22
Expiry date	2028-05-23
Frankfurt am Main,	2024-03-22

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-MDR-094

DQS Medizinprodukte GmbH

Sigrid Uhlemann
Managing Director

Michael Bothe
Head of Certification Body
(active medical devices)

Szymon Kurdyn
Head of Certification Body
(non-active medical devices)

Accredited Body: DQS Medizinprodukte GmbH, August-Schanz-Str. 21, 60433 Frankfurt am Main
DQS Medizinprodukte GmbH is a Notified Body according to Regulation (EU) 2017/745 of the Council concerning medical devices with the Identification Number 0297.
The validity of this certificate can only be verified by the QR-code.

420.90 Version 6.0

Annex to EU Quality Management Certificate
SRN of Manufacturer: CH-MF-000025018
Certificate ID: 1000167723

Authorised Representative of the company:

Ziemer Ophthalmology (Deutschland) GmbH

Kronenstr. 38
79211 Denzlingen
Germany

SRN: DE-AR-000005638

Device categories and variants covered by this certificate:

Device category:	**MDA 0302 - Active non-implantable devices utilising non-ionizing radiation**
Product name:	510.003.002 FEMTO LDV Z2 510.003.004 FEMTO LDV Z4 510.003.006 FEMTO LDV Z6 510.003.008 FEMTO LDV Z8 510.003.009 FEMTO Z8 NEO
Risk classification:	IIb
Basic-UDI-DI:	764016775FLMDEVGN
Intended purpose:	Resection of the cornea or of the ocular surface

Device category:	**MDN 1206: Non-active non-implantable ophthalmologic devices**
Product name:	510.700.2xx -- Suction Ring Mounting Set for (Lasik, Corneal Surgery, Adv.Corneal Surgery) [z-axis] 510.710.1xx -- Suction Ring Mounting Set, (no z-axis) 510.710.15x, 510.710.160 -- LCS Suction Ring Mounting Set 510.710.3xx, 510.710.605 -- LCS Intershield (containing 510.710.2xx, 510.710.4xx, 510.710.505, 510.710.705) 510.700.117, 510.700.119 -- Procedure Pack for Cataract Surgery 510.700.01x, 510.700.02x -- Procedure Pack for Corneal Surgery (containing 510.700.11x, 510.700.12x) 510.700.118, 510.700.124 – Procedure Pack for Corneal Surgery Liquid 510.701.270 -- Suction Tubing 510.701.220 -- Casing Set
Risk classification:	IIa
Basic-UDI-DI:	764016775PPACKSKP
Intended purpose:	Resection of the cornea or of the ocular surface

Examinations and tests performed:
333427 A209785MED MDR2017Q dated 2023-05-12
540641 A211475MED MDR2017B dated 2023-05-12
333427 A211475MED MDR2017B FEMTO Procedure Packs dated 2023-12-18

Further conditions for or limitations to the validity of the certificate:
n/a

Annex to EU Quality Management Certificate
SRN of Manufacturer: CH-MF-000025018
Certificate ID: 1000167723

Reference to previous certificates:

Revision	Date of Issue	Certificate-ID	Description of change
01	2023-05-24	1000114837	Addition of FEMTO Procedure Packs
02	2023-12-22	1000156974	New certificate template