CERTIFICATE

This is to certify that the company

Ziemer Ophthalmic Systems AG

also trading as
SIE AG, Surgical Instrument Engineering
SIS Ltd., Surgical Instrument Systems and
SMT Swiss Microtechnology AG

Allmendstrasse 11
2562 Port
Switzerland

with the organizational units/sites as listed in the annex
has implemented and maintains a **Quality Management System**.

Scope of certification:
Design and development, manufacturing, distribution, installation and service of sterile and non sterile, active and non active medical devices for the ophthalmology.
-**AUS (a), BRA, CND, JPN, USA (a,b,c,d)**

Through an audit, documented in a report, performed by DQS Medizinprodukte GmbH, it was verified that the management system fulfills the requirements of the following standard:

ISO 13485 : 2016

including applicable country-specific regulatory requirements, as indicated below the scope (full references of abbreviations are listed in the annex)

Certificate registration no.	540641 MDSAP16
Certificate unique ID	1000172736
Effective date	2024-12-26
Expiry date	2027-12-25
Frankfurt am Main	2024-09-27

MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

DQS Medizinprodukte GmbH

Sigrid Uhlemann
Managing Director

Marc Goedecke
Product Manager

Annex to certificate
Certificate registration No.: 540641 MDSAP16
Certificate unique ID: 1000172736
Effective date: 2024-12-26

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Audited site	REPs FEI No.: site scope and country-specific requirements
540532 **Ziemer Ophthalmic Systems AG** Allmendstrasse 11 2562 Port Switzerland	Design and development, manufacturing, distribution, installation and service of sterile and non sterile, active and non active medical devices for the ophthalmology. -**AUS (a), BRA, CND, JPN, USA (a,b,c,d)** **REPs FEI No: F002426**
540874 **SIS Ltd., Surgical Instrument Systems** Allmendstrasse 11 2562 Port Switzerland	Design, development, manufacturing, distribution, installation and service of sterile and non sterile, active and non active medical devices for the ophthalmology -**AUS (a), BRA, CND, JPN, USA (a,b,c,d)** **REPs FEI No: F002426**
522012 **SMT Swiss Microtechnology AG** Allmendstrasse 11 2562 Port Switzerland	Design and development, manufacturing, installation, distribution and service of sterile and non sterile, active and non active medical devices for the ophthalmology. -**AUS (a), BRA, CND, JPN, USA (a,b,c,d)** **REPs FEI No: F002426**
522014 **SIE AG , Surgical Instrument Engineering** Allmendstrasse 11 2562 Port Switzerland	Design and development, manufacturing, distribution, installation and service of sterile and non sterile, active and non active medical devices for the ophthalmology. **-AUS (a), BRA, CND, JPN, USA (a,b,c,d)** **REPs FEI No: F002426**

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Audited site	REPs FEI No.: site scope and country-specific requirements
540555 **Ziemer Ophthalmic Systems AG** Erlenstrasse 31 2555 Brügg Switzerland	Manufacturing, distribution and service of sterile and non sterile, active and non active medical devices for the ophthalmology. **-AUS (a), BRA, CND, JPN, USA (a,b,c,d)** **REPs FEI No: F002434**
522015 **SIE AG , Surgical Instrument Engineering** Erlenstrasse 31 2555 Brügg Switzerland	Manufacturing and distribution of sterile and non sterile, active and non active medical devices for the ophthalmology. **-AUS (a), BRA, CND, JPN, USA (a,b,c,d)** **REPs FEI No: F002434**
540875 **SIS Ltd., Surgical Instrument Systems** Erlenstrasse 31 2555 Brügg Switzerland	Manufacturing, distribution and service of sterile and non sterile, active and non active medical devices for the ophthalmology. **-AUS (a), BRA, CND, JPN, USA (a,b,c,d)** **REPs FEI No: F002434**
066412 **SMT Swiss Microtechnology AG** Erlenstrasse 31 2555 Brügg Switzerland	Manufacturing, distribution and service of sterile and non sterile, active and non active medical devices for the ophthalmology. **-AUS (a), BRA, CND, JPN, USA (a,b,c,d)** **REPs FEI No: F002434**

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Full references of country-specific requirements of MDSAP participating Regulatory Authorities

Abbreviation	Jurisdiction	Reference
AUS	Australia	(a) Therapeutic Goods (Medical Devices) Regulations 2002, Schedule 3, Part 1 – Full Quality Assurance Procedure (b) Therapeutic Goods (Medical Devices) Regulations 2002, Schedule 3, Part 4 – Production Quality Assurance Procedure
BRA	Brazil	RDC ANVISA n. 665/2022 RDC ANVISA n. 551/2021 RDC ANVISA n. 67/2009
CND	Canada	Medical Device Regulations SOR/98-282, Part 1
JPN	Japan	MHLW Ministerial Ordinance No. 169 (2004) as amended by MHLW Ordinance No. 128 (2014), Articles 4 to 68 Japan PMD Act (as applicable)
USA	United States	(a) 21 CFR Part 803 (b) 21 CFR Part 806 (c) 21 CFR Part 807 (d) 21 CFR Part 820 (e) 21 CFR Part 821