CERTIFICATE

This is to certify that the company

HEINE Optotechnik GmbH & Co. KG

Dornierstr. 6
82205 Gilching
Germany

with the organizational units/sites as listed in the annex

has implemented and maintains a **Quality Management System**.

Scope of certification:
Design & Development, Production, Distribution and Repair of Otoscopes, ENT Speciality Instruments, Ophthalmologic Instruments, Laryngoscopes, Dermatologic Instruments, Sphygmomanometers and Stethoscopes, Proctological Instruments, Examination Lights, Binocular Loupes, Headlights, Fibre Optic Projectors, Power Sources and accessories of mentioned products.
-AUS (b), 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.	325735 MDSAP16
Certificate unique ID	1000170221
Effective date	2025-01-28
Expiry date	2028-01-27
Frankfurt am Main	2025-01-25

MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

DQS Medizinprodukte GmbH

Heinrich von Mettenheim
Managing Director

August-Schanz-Straße 21, 60433 Frankfurt am Main,
Tel. +49 (0) 69 95427-300, info-med@dqs.de
DQS Medizinprodukte GmbH is recognized under the Medical Devices Single Audit Program.
Visit https://www.dqs.de/en/customer-database/ to validate this certificate.
The validity of the certification can only be verified by the QR-code.

413.01 Version 7.0

Annex to certificate
Certificate registration No.: 325735 MDSAP16
Certificate unique ID: 1000170221
Effective date: 2025-01-28

HEINE Optotechnik GmbH & Co. KG

Dornierstr. 6
82205 Gilching
Germany

Audited site	REPs FEI No.: site scope and country-specific requirements
HEINE Optotechnik GmbH & Co. KG Dornierstr. 6 82205 Gilching Germany	Design & Development, Production, Distribution and Service of Otoscopes, ENT Speciality Instruments, Ophthalmologic Instruments, Laryngoscopes, Dermatologic Instruments, Sphygmomanometers and Stethoscopes, Proctological Instruments, Examination Lights, Binocular Loupes, Headlights, Fibre Optic Projectors, Power Sources and accessories of mentioned products. -**AUS (b), BRA, CND, JPN, USA (a,b,c,d)** **REPs FEI No.: F001507**

Annex to certificate
Certificate registration No.: 325735 MDSAP16
Certificate unique ID: 1000170221
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HEINE Optotechnik GmbH & Co. KG

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82205 Gilching
Germany

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 Devices Regulations – Part 1- SOR 98/282 Medical Devices Regulations – Part 1.1 – SOR 98/282 (as applicable)
JPN	Japan	MHLW Ministerial Ordinance 169, Article 4 to Article 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