



# 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 Oscopes, 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



## DQS Medizinprodukte GmbH

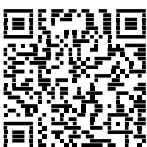
Heinrich von Mettenheim  
Managing Director

August-Schanz-Straße 21, 60433 Frankfurt am Main,  
Tel. +49 (0) 69 95427-300, [info-med@dqs.de](mailto: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.





**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**

**HEINE Optotechnik GmbH & Co. KG**  
Dornierstr. 6  
82205 Gilching  
Germany

### **REPs FEI No.: site scope and country-specific requirements**

Design & Development, Production, Distribution and Service of Oscopes, 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**  
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### **Full references of country-specific requirements of MDSAP participating Regulatory Authorities**

<b>Abbreviation</b>	<b>Jurisdiction</b>	<b>Reference</b>
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