



CERTIFICATE



This is to certify that the company



HEINE Optotechnik GmbH & Co. KG

Kientalstraße 7
82211 Herrsching
Germany

with the organizational units/sites as listed in the annex

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

Scope:

Design, Research & 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.

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:

DIN EN ISO 13485 : 2016 + AC : 2017-07
EN ISO 13485 : 2016 + AC : 2016
ISO 13485 : 2016

Certificate registration no.	325735 MP2016
Certificate unique ID	170715630
Effective date	2019-01-28
Expiry date	2022-01-27
Frankfurt am Main	2019-01-28



DQS Medizinprodukte GmbH

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Managing Director

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Head of Certification Body

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Annex to certificate

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HEINE Optotechnik GmbH & Co. KG

Kientalstraße 7
82211 Herrsching
Germany

Location

Scope

**HEINE Optotechnik GmbH & Co. KG
Entwicklung/Konstruktion (Werk 5)**
Arzberger Str. 10
82211 Herrsching
Germany

Design, Research & Development

**HEINE Optotechnik GmbH & Co. KG
Produktion (Werk 2)**
Arzberger Str. 4
82211 Herrsching
Germany

Production, Service, Testing

**HEINE Optotechnik GmbH & Co. KG
Zentrale (Werk 1)**
Kientalstraße 7
82211 Herrsching
Germany

Headquarter, Optics Production, Testing

**HEINE Optotechnik GmbH & Co. KG
Spritzerei/Lehrwerkstatt (Werk 3)**
Seefelder Str. 7
82211 Herrsching
Germany

Thermal Plastic Injection Molding,
Apprenticeship Workshop, Tool & Die
Production, Utilities & Equipment Design and
Production, Testing

**HEINE Optotechnik GmbH & Co. KG
Werkstatt (Werk 4)**
Wörthseestr. 3
83254 Breitbrunn
Germany

Machine Workshop