CERTIFICATE

This is to certify that the company

SCHOELLY- OPTIX OOD

Krastyo Geshanov 30
4500 Panagyurishte
Bulgaria

with the organizational units/sites as listed in the annex

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

Scope of certification:
Manufacturing of endoscopes and endoscopic accessories, light sources, TV-camera-systems, fiber optic, optic and opto-mechatronic components, units and systems, optical-fiberoptical sensors, visualization systems for aid in the diagnosis, cable technology and cable assembly for medical devices.
-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.	540889 MDSAP16
Certificate unique ID	1000135349
Effective date	2023-06-30
Expiry date	2026-06-29
Frankfurt am Main	2023-06-30

MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

DQS Medizinprodukte GmbH

Sigrid Uhlemann
Managing Director

Marc Goedecke
Product Manager

Annex to certificate
Certificate registration No.: 540889 MDSAP16
Certificate unique ID: 1000135349
Effective date: 2023-06-30

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Audited site	REPs FEI No.: site scope and country-specific requirements
SCHOELLY-OPTIX OOD Technology Park OPTIX-CO 4500 Panagyurishte Bulgaria	Manufacturing of endoscopes and endoscopic accessories, light sources, TV-camera-systems, fiber optic, optic and opto-mechatronic components, units and systems, optical-fiberoptical sensors, visualization systems for aid in the diagnosis, cable technology and cable assembly for medical devices. **-JPN, USA (a,b,c,d)** **REPs FEI No.: F005732**
SCHOELLY-OPTIX OOD Krastyo Geshanov 30 4500 Panagyurishte Bulgaria	Manufacturing of endoscopes and endoscopic accessories, light sources, TV-camera-systems, fiber optic, optic and opto-mechatronic components, units and systems, optical-fiberoptical sensors, visualization systems for aid in the diagnosis, cable technology and cable assembly for medical devices. **-JPN, USA (a,b,c,d)** **REPs FEI No.: F005732**

Annex to certificate
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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