CERTIFICATE

This is to certify that the company

SCHÖLLY FIBEROPTIC GMBH

Robert-Bosch-Str. 1 - 3
79211 Denzlingen
Germany

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 and service 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 and MIS (Minimally Invasive Surgery) instruments for the visualization in the fields of ENT, gynecology, urology, gastroenterology, orthopedics and general in plastic surgery.
-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.	058247 MDSAP16
Certificate unique ID	1000115378
Effective date	2023-07-05
Expiry date	2026-07-04
Frankfurt am Main	2023-07-05

DQS Medizinprodukte GmbH

Sigrid Uhlemann
Managing Director

Marc Goedecke
Product Manager

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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 this certificate can only be verified by the QR-code.

413.01 Version 6.0

Annex to certificate
Certificate registration No.: 058247 MDSAP16
Certificate unique ID: 1000115378
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Audited site	REPs FEI No.: site scope and country-specific requirements
494503 **SCHÖLLY FIBEROPTIC GMBH** Robert-Bosch-Str. 1 - 3 79211 Denzlingen Germany	Administration, human resources, information technology and finance to support the organization´s design and development, manufacturing, distribution and service 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 and MIS (Minimally Invasive Surgery) instruments for the visualization in the fields of ENT, gynecology, urology, gastroenterology, orthopedics and general in plastic surgery. -**AUS (a), BRA, CND, JPN, USA (a,b,c,d)** **REPs FEI No.: F000640**
548364 **SCHÖLLY FIBEROPTIC GMBH** Robert-Bunsen-Str. 4 79211 Denzlingen Germany	Design and development, manufacturing, purchasing, distribution, service, quality management, quality assurance and regulatory affairs 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 and MIS (Minimally Invasive Surgery) instruments for the visualization in the fields of ENT, gynecology, urology, gastroenterology, orthopedics and general in plastic surgery. -**AUS (a), BRA, CND, JPN, USA (a,b,c,d)** **REPs FEI No.: F000640**

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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