EU-Quality Management Certificate

This is to certify that the company

SCHÖLLY FIBEROPTIC GMBH

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

has implemented a complete Quality Management System for each phase from Design to Final Testing of the products.

Through an audit, documented in a report, carried out by DQS Medizinprodukte GmbH, the proof was provided that this quality management system meets the requirements according to

Annex IX of the Regulation (EU) 2017/745

CONFORMITY ASSESSMENT PROCEDURE ON THE BASIS OF A QUALITY MANAGEMENT SYSTEM AND AN ASSESSMENT OF THE TECHNICAL DOCUMENTATION

regarding the medical devices listed in the Annex:
The manufacturer shall be subject to surveillance in accordance with Annex IX, Chapter 1, Section 3.
The CE marking with the identification number of the Notified Body (0297) may be affixed on the devised listed on the certificate.

In case of devices placed on the market in sterile condition, devices with a measuring function or for devices which are reusable surgical instruments, the involvement of the Notified Body in these procedures shall be limited: in case of products that are placed on the market in sterile condition, limited to the aspects of manufacture concerned with securing and maintaining sterile condition; in the case of devices with a measuring function limited to the aspects related to the conformity of the devices with the metrological requirements; in the case of reusable surgical instruments limited to the aspects related to reuse, in particular cleaning, disinfection, sterilisation, maintenance and functional testing, as well as the related instructions for use.

Certificate registration no.	DE-MF-000005618
Certificate ID	170774483
Previous certificate-ID	n/a
Effective date	2022-04-28
Expiry date	2027-04-27
Frankfurt am Main,	2022-04-28

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-MDR-094

DQS Medizinprodukte GmbH

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DQS Medizinprodukte GmbH is a Notified Body according to Regulation (EU) 2017/745 of the Council concerning medical devices with the Identification Number 0297.

420.90 Version 1.0

Annex to EU Quality Management Certificate
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Product name	Risk class	Intended Use
Instruments for Hysteroscopy	IIa	The hysteroscopes are used when performing endoscopic, diagnostic and therapeutic surgical procedures. Examples of the use of the devices include visualization and tissue manipulation as long as this is considered appropriate by the surgeon. The hysteroscopes are intended to be used in gynecological surgery. The cervix is used for minimally-invasive access
Instruments for Laparoscopy	IIa	Rigid endoscopes without a working channel permit visualization of the inside of the body and body cavities. Laparoscopes are used to visualize the abdominal cavity and the organs within it.
Instruments for Arthroscopy	IIa	Rigid endoscopes without a working channel permit visualization of the inside of the body and body cavities. Arthroscopes are intended for use in minimally invasive orthopedic procedures. They are used to visualize and illuminate particular regions of the body during diagnostic and therapeutic procedures. They are used in particular for procedures on the knee, shoulder, jaw, wrist, ankle and elbow, for example.
Instruments for Cystoscopy	IIa	The cystoscopes are indicated to provide the user with the means for endoscopic diagnostic and therapeutic surgical procedures. The cystoscopes are intended to be used in general urological surgery through a minimally invasive approach by utilizing natural orifices to access the surgical site.
Instruments for Sinuscopy	IIa	Rigid endoscopes without a working channel permit visualization of the inside of the body and body cavities. Sinuscopes are intended for use in otorhinolaryngology, head and neck surgery. They are used to visualize and illuminate particular body cavities during diagnostic and therapeutic procedures. These include the frontal, maxillary and nasal sinuses.
Instruments for Laparoscopy	IIa	Videoendoscopes without a working channel permit visualization of the inside of the body and body cavities. Videolaparoscopes are used to visualize the abdominal cavity and the organs within it

Examinations and tests performed (e.g. Reference to relevant CS, harmonised standards, test reports and audit report):
058247_A207649MED_stage2_V1.1 dated 2021-10-02

Reference to the relevant parts of the technical documentation or other certificates required for the placing on the market of the device or devices covered:
n/a