



CERTIFICATE



This is to certify that the company

SI US INSTRUMENTS GmbH

Max-Planck-Str. 3
12489 Berlin
Germany

with the organizational units/sites as listed in the annex
has implemented and maintains a **Quality Management System**.

Scope:

Manufacture and distribution of holding and cutting sterile and non-sterile disposable surgical instruments as well as probes, suction cannulas and cannulas made of stainless steel.

Manufacture and distribution of sterile surgical sets, wound care products and wound care sets for the medical sector:

- General surgery
- Orthopaedics and Trauma Surgery
- Gynaecology
- Urology
- Thoracic surgery
- Visceral surgery
- Ophthalmology
- ENT
- Cardiovascular surgery
- Plastic and aesthetic surgery

Cleaning, disinfection, assembly, packaging, sterilization and distribution of invasive medical devices for
• Osteosynthesis

- Orthopaedics and Trauma Surgery

Cleaning, disinfection, assembly, packaging, sterilisation and distribution of surgical products

- Dressing materials
- Patient and device covers
- Surgical clothing
- Trays and plastic instruments
- Surgical tubes and bags
- Syringes and cannulas

- Medical articles and sets for ward and practice use

Design and manufacture of sterile barrier systems, packaging components and packaging systems as well as the implementation of packaging qualifications including shelf-life determination.

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. 515948 MP2016

Certificate unique ID 170761409

Effective date 2020-08-25

Expiry date 2023-08-24

Frankfurt am Main 2020-07-27



Deutsche
Akkreditierungsstelle
D-ZM-16021-01-00

DQS Medizinprodukte GmbH

Sigrid Uhlemann
Managing Director

Dr. Thomas Feldmann
Head of Certification Body



Annex to certificate
Certificate registration No.: 515948 MP2016
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SI US INSTRUMENTS GmbH

Ul. Lotnicza 8A
55-050 Sobotka
Mirosławice
Poland

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