



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, Maxillofacial 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

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 : 2018
ISO 13485 : 2016

Certificate registration no.	515948 MP2016
Certificate unique ID	170782076
Effective date	2023-08-25
Expiry date	2026-08-24
Frankfurt am Main	2023-06-27



DQS IS A MEMBER OF



DQS Medizinprodukte GmbH

Sigrid Uhlemann
Managing Director

Szymon Kurdyn
Product Manager



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



Annex to certificate
Certificate registration No.: 515948 MP2016
Certificate unique ID: 170782076
Effective date: 2023-08-25

SI US INSTRUMENTS GmbH

Max-Planck-Str. 3
12489 Berlin
Germany

Location

527913
SI US INSTRUMENTS GmbH
Max-Planck-Str. 3
12489 Berlin
Germany

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

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525863
SI US Polska Sp. z o. o.
Nowa 21, Nowa
Wies Wroclawska
55-080 Kąty Wrocławskie
Poland

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527913
Si Us Instruments GmbH
Am Spitzberg 6
15834 Rangsdorf
Germany

Warehouse