



THE INTERNATIONAL CERTIFICATION NETWORK

CERTIFICATE

DQS Holding GmbH has issued an IQNet recognized certificate that the organization

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**.

for the following 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..

which fulfils the requirements of the following standard:

DIN EN ISO 13485 : 2016 + AC : 2017-07
EN ISO 13485 : 2016 + AC : 2016
ISO 13485 : 2016

Issued on: 2020-08-25
Expires on: 2023-08-24

This attestation is directly linked to the IQNet Partner's original certificate and shall not be used as a stand-alone document.

Registration number: DE-515948 MP2016

Alex Stoichitoiu
President of IQNet

Michael Drechsel
Managing Director of
DQS Holding GmbH



IQNet Partners*:

AENOR Spain AFNOR Certification France APCER Portugal CCC Cyprus CISQ Italy
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SIRIM QAS International Malaysia SQS Switzerland SRAC Romania TEST St Petersburg Russia TSE Turkey YUQS Serbia

* The list of IQNet partners is valid at the time of issue of this certificate. Updated information is available under www.iqnet-certification.com

Annex to IQNet Certificate Number: 515948 MP2016

SI US INSTRUMENTS GmbH

Max-Planck-Str. 3
12489 Berlin
Germany

Location

Scope

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12489 Berlin
Germany

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

SI US INSTRUMENTS GmbH
Ul. Lotnicza 8A
55-050 Sobotka
Miroslawice
Poland

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