

Certificate

We hereby certify the company

Si Us Instruments® GmbH
Max-Planck-Str. 3
12489 Berlin
Germany



with the sites listed in the attachment the introduction and application of a

Quality management system according to EN ISO 13485

in the scope

Assembling, distribution, and storage of sterile procedure packs for medical, diagnostic, and surgical procedures

Trade in sterile surgical instruments as well as sterile cannulas

Service provider for the cleaning, assembly, packaging, sterilization, storage of medical devices in the fields of general surgery, orthopaedics and trauma surgery, emergency surgery, ophthalmology, gynaecology, urology, thoracic surgery, visceral surgery, ENT medicine, cardiovascular surgery, and plastic and aesthetic surgery

Service provider for the storage of medical devices

An audit by mdc has proven that this quality management system meets the requirements of the following standard:

EN ISO 13485:2016 + AC:2018 + A11:2021 - ISO 13485:2016
Medical devices – Quality management systems – Requirements for regulatory purposes

Valid from 2026-04-13
Valid until 2028-04-01

Registration No. D1521800003
Report No. P25-00917-341997

Stuttgart, 2026-04-13



Certification Body



Sites included in the certification:

Location	Scope
Si Us Instruments® GmbH Max-Planck-Str. 3 12489 Berlin Germany	Assembling, distribution, and storage of sterile procedure packs for medical, diagnostic, and surgical procedures Trade in sterile surgical instruments as well as sterile cannulas Service provider for the cleaning, assembly, packaging, sterilization, storage of medical devices in the fields of general surgery, orthopaedics and trauma surgery, emergency surgery, ophthalmology, gynaecology, urology, thoracic surgery, visceral surgery, ENT medicine, cardiovascular surgery, and plastic and aesthetic surgery Service provider for the storage of medical devices
Si Us Instruments® GmbH Am Spitzberg 6 15834 Rangsdorf Germany	Storage of sterile procedure packs for medical, diagnostic, and surgical procedures Service provider for the storage of medical devices
Si Us Instruments® Sp. z.o.o. Nowa Wies Wroclawska Nowa 21 55-080 Katy Wroclawskie Poland	Assembling, distribution, and storage of sterile procedure packs for medical, diagnostic, and surgical procedures Service provider for the cleaning, assembly, packaging, sterilization, storage of medical devices in the fields of general surgery, orthopaedics and trauma surgery, emergency surgery, ophthalmology, gynaecology, urology, thoracic surgery, visceral surgery, ENT medicine, cardiovascular surgery, and plastic and aesthetic surgery

Stuttgart, 2026-04-13



MDC
Certification Body