



# EC-CERTIFICATE

(Production quality assurance)



This is to certify that the company

## SI US INSTRUMENTS GmbH

Max-Planck-Str. 3  
12489 Berlin  
Germany

has implemented and maintains a quality assurance system which applies to the manufacture and final controls of the products.

Through an audit, documented in a report, performed by DQS Medizinprodukte GmbH, it was verified that the management system fulfills the requirements of

### Annex V of Council Directive 93/42/EEC concerning medical devices

with respect to the following medical devices:

Sterile single use instruments, Sterile sets /sterile wound care sets according to annex Class IIa  
consisting of  
cutting and holding surgical instruments as well as probes, suction cannulas and  
cannulas  
dressing materials  
OP-covers  
OP clothing  
Trays and plastic clamps  
OP tubes, bags and connectors  
Syringes  
Other surgical materials in different configurations.

The manufacturer is subject to surveillance according to Annex V, Section 4. The CE marking with the Notified Body Identification Number (0297) may be affixed on the devices listed in the certificate. The certificate is in the case of class I(s) devices (I(s) = class I products placed on the market in sterile conditions) limited to the aspects of manufacture concerned with securing and maintaining sterile conditions. The certificate is in the case of class I(m) devices (I(m) = class I devices with a measuring function) limited to the aspects of manufacture concerned with the conformity of the products with the metrological requirements.

Certificate registration no.	515948 MR5
Certificate unique ID	170762296
Effective date	2020-07-27
Expiry date	2024-05-26
Frankfurt am Main	2020-07-27

### DQS Medizinprodukte GmbH

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DQS Medizinprodukte GmbH is a Notified Body according to Council Directive 93/42/EEC concerning medical devices with the Identification Number 0297.



**Annex to certificate**  
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<b>Device family</b>	<b>Device</b>	<b>Class</b>
<b>Sterile single use instruments</b>	Cannulae	Ila
	Chisels	Ila
	Clamps	Ila
	Dilators	Ila
	Drills	Ila
	Elevators	Ila
	Forceps	Ila
	Hooks	Ila
	Knife Handles	Ila
	Knives, Scalpel	Ila
	Needle Holders	Ila
	Osteotomes	Ila
	Cutters, Pin and Wire	Ila
	Probes	Ila
	Raspatories	Ila
	Retractors	Ila
	Routers, Bone Cutting	Ila
	Saws	Ila
	Scissors	Ila
	Screwdrivers, Bone	Ila
Cutters	Ila	
Specula	Ila	
Explorers	Ila	

This annex is only valid in connection with the above-mentioned certificate.



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<b>Device family</b>	<b>Device</b>	<b>Class</b>
<b>Sterile Sets</b>	<b>Sets</b>	<b>Ila</b>