



# EC-CERTIFICATE

(Full quality assurance system)



This is to certify that the company

**KLS martin**  
GROUP

## Gebrüder Martin GmbH & Co. KG

KLS Martin Platz 1  
78532 Tuttlingen  
Germany

has implemented and maintains a full quality assurance system which applies to the products at every stage from design to final controls.

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

### Annex II – excluding Section 4 of Council Directive 93/42/EEC concerning medical devices

with respect to the following medical devices:

Active and non active medical devices, surgical instruments and units, implants, medical devices for RF- and laser surgery, Smoke evacuation systems, Accessories for Smoke evacuation systems, ceiling-mounted supply systems and accessories according to annex.

The manufacturer is subject to surveillance according to Annex II, Section 5. The CE marking with the Notified Body Identification Number (0297) may be affixed on the devices listed in the certificate. An EC Design Examination Certificate according to Annex II, Section 4 is required for class III devices covered by this 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.	210299 MR2
Certificate unique ID	170738701
Effective date	2019-06-25
Expiry date	2022-05-12
Frankfurt am Main	2019-06-25

### DQS Medizinprodukte GmbH

Sigrid Uhlemann  
Managing Director

Dr. Thomas Feldmann  
Head of Certification Body

August-Schanz-Straße 21, 60433 Frankfurt am Main,  
Tel. +49 (0) 69 95427-300, [medical.devices@dqs-med.de](mailto:medical.devices@dqs-med.de)

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**  
**Certificate registration No.: 210299 MR2**  
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<b>Device family</b>	<b>Devices</b>	<b>Class</b>
RF-surgery units	Medical RF-surgery units for general and special applications Argon Beamer	IIb
Accessories for RF-surgery units	Handles for RF-surgery Electrodes Forceps and scissors Clamps, forceps, NervScout	IIb IIa / IIb
Laser surgery units	surgical laser units for common and particular use	IIb
Accessories for laser surgery units	Laser contact probe Adapter for laser fibres Connection fibres Fibre optics Bipolar suction and irrigation units Micromanipulator	IIa / IIb
Smoke evacuation systems	products for smoke evacuation	IIa
Accessories for Smoke evacuation systems	adapters	IIa
Implants and Instruments	Distractor Trocar tip for activation arm Condylar implant Washers Meshes (for cranioplasty) Bone plates Bone screws Bone nails Fixation screws Fixation screws (lug) UHP (prosthesis for wrist joint) Tantal wire (orthodontic) Bone clips Bone wire Sternal Talon Finger joint CranioXpand	IIa / IIb
	Aneurysm Clip system permanent and temporary	III



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<b>Device Family</b>	<b>Device</b>	<b>Class</b>
Resorbable Implants	Resorb X meshes Resorb X plates Resorb X screws Resorb X Pins	III
Surgical instruments and units	Sterile scalpels Sterile blades Guide pins Guide wires	Ila Ila Iib Iib
	Drill bits OMF surgery BOS driver SonicWeld Rx (basis device, handpieces) SonicWeld Rx (sonotrodes) Drill bits / Saw blades orthopaedic BOS-Battery pack sterile Bending Templates	Ila Ila Ila Ila Ila Is Is
Pendants	Service Head	Iib
Wound spreading systems	marTract	Ila
Surgical Instruments and units	Suction Units, Suction Cannulae, Irrigation Cannulae	Ila