



# EC-CERTIFICATE

(Full quality assurance system)



This is to certify that the company

**KLS martin**  
GROUP

## Karl Leibinger Medizintechnik GmbH & Co. KG

Kolbinger Straße 10  
78570 Mühlheim  
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 and implants according 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.	071006 MR2
Certificate unique ID	170672842
Effective date	2017-05-13
Expiry date	2022-05-12
Frankfurt am Main	2017-05-13

### DQS Medizinprodukte GmbH

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Dr. Thomas Feldmann  
Head of Certification Body

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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## **Karl Leibinger Medizintechnik GmbH & Co. KG**

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<b>Device family</b>	<b>Device</b>	<b>Class</b>
Surgical instruments and units	Drill bits OMF surgery	Ila
	BOS Driver	Ila
	SonicWeld Rx (basis device, handpieces)	Ila
	SonicWeld Rx (sonotrodes)	Ila
	BOS-Batteriepack steril	Is
	Suction Tubes	Ila
	Rib Spreaders	Ila
	Retractors	Ila
	Insufflation Cannulas	Ila
Angled Screwdriver	Ila	
Implants	Distractors	Ilb
	Condylar implants	Ilb
	Washers	Ilb
	Meshes (for cranio-plasty)	Ilb
	Bone plates	Ilb
	Bone screws	Ilb
	Fixation screws	Ilb
	Fixation screws (lug)	Ilb