



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	170739406
Effective date	2019-06-25
Expiry date	2022-05-12
Frankfurt am Main	2019-06-25

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