



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, HF- and laser surgery, 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	170592939
Effective date	2014-05-27
Expiry date	2019-05-26
Frankfurt am Main	2014-05-20

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	Devices	Class
Surgical instruments and units	Sterile scalpels	IIa
	Sterile blades	IIa
	Guide pins	IIa
	Guide wires	IIa
	Drill bits OMF surgery	IIa
	BOS driver	IIa
	SonicWelder Rx	IIb
	Drill bits / Saw blades orthopaedic	IIa
	BOS-Battery pack sterile	Is
	Bending Templates	Is
Pendants	Service Head	IIb
Bone Grafting Material	Martrix	III
Suture Material and Clamps	Wound Clips	IIa
Nerve-location system	Nerve tester	IIb