



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	170763177
Effective date	2020-01-13
Expiry date	2024-05-26
Frankfurt am Main	2020-01-13

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
RF-surgery units	Medical RF-surgery units for general and special applications	IIb
Accessories for RF-surgery units	Argon Beamer 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 Trocator 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 Finger joint CranioXpand marPOR Polyethylene Implants	IIa / IIb



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