



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	170776073
Effective date	2021-05-14
Expiry date	2024-05-26
Frankfurt am Main	2021-05-14

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.



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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	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 Finger joint CranioXpand marPOR Polyethylene Implants K-Wires Foot Osteosynthesis System Pelvis Fixation System	IIa / IIb



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Device Family	Device	Class
Resorbable Implants Resorb X®	Resorb X / xG / xC Plates Resorb X / xG / xC Meshes Resorb X / xG / xC Foils Resorb X / xC Membranes Resorb X / xG / xC 3D Implants Resorb X / xC Screws Resorb X / xG / xC Pins Resorb X Suture Anchor	III
Resorbable Implants Resorb X® - SonicWeld Spine	SonicWeld Spine Rx / xG Plates SonicWeld Spine Rx / xG Meshes SonicWeld Spine Rx / xG Foils SonicWeld Spine Rx 3D Implants SonicWeld Spine Rx / xG Pins SonicWeld Spine Rx Suture Anchor	III
	HBS 2 Resorb Mg	III
Surgical instruments and units	Sterile scalpels Sterile blades Guide pins Guide wires Drill bits OMF surgery BOS driver SonicWeld Rx (basis device, handpieces) SonicWeld Rx (sonotrodes) Drill bits Repositioning Instruments BOS-Battery pack sterile Screwdriver blades Bending Templates Rotating cutting devices Angled screwdriver	Ila Ila Ilb Ilb Ila Ila Ila Ila Ila Is Ila Ila Ila Ila
Pendants	Service Head	Ilb
Surgical Instruments and units	Suction Units, Suction Cannulae, Irrigation Cannulae marTract Wound spreading systems	Ila Ila Ila