



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 | 170680117 |
| 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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| 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 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 Sternal Talon Finger joint | IIa / IIb |
| | Aneurysm Clip system permanent and temporary | III |



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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 | IIa |
| | Sterile blades | IIa |
| | Guide pins | IIb |
| | Guide wires | IIb |
| | Drill bits OMF surgery | IIa |
| | BOS driver | IIa |
| | SonicWeld Rx (basis device, handpieces) | IIa |
| | SonicWeld Rx (sonotrodes) | IIa |
| | Drill bits / Saw blades orthopaedic | IIa |
| | BOS-Battery pack sterile | Is |
| | Bending Templates | Is |
| | Pendants | Service Head |
| Wound spreading systems | marTract | IIa |