EC-CERTIFICATE

(Full quality assurance system)

This is to certify that the company

KLS martin
GROUP

KLS Martin GmbH + Co. KG

Am Flughafen 18
79108 Freiburg
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:

Medical RF-, Laser units for surgery, Smoke evacuation systems and accessories, sterile or non sterile 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.	247860 MR2
Certificate unique ID	170770416
Effective date	2020-06-25
Expiry date	2024-05-26
Frankfurt am Main	2020-06-25

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
RF surgery units	Medical RF surgery units for general and particular use; Argon-Beamer	IIb
Accessories for RF surgery	Devices for RF surgery: electrodes, tweezers, scissors, clamps, forceps, Argon accessories, sealing intruments	IIa / IIb
Smoke evacuation systems	Products for smoke evacuation	IIa
Accessories for smoke evacuation systems	adapters	IIa
Laser surgery units	surgical laser units for common and particular use	IIb
Accessories for laser surgery	Fibers, sterile or non sterile Fiber adapters Catheter supply kits with accessories suction and irrigation pumps with accessories	IIa / IIb