EC-CERTIFICATE

(Full quality assurance system)

This is to certify that the company

Stockert GmbH

Bötzinger Straße 72
79111 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:

Sterile catheter connection cables, surgical and auxiliary surgical devices and devices for stimulation according 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.	288842 MR2
Certificate unique ID	170696999
Effective date	2017-11-25
Expiry date	2022-03-18
Frankfurt am Main	2017-11-25

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.

411.20 Version 1.0

Annex to certificate
Certificate registration No.: 288842 MR2
Certificate unique ID: 170696999
Effective date: 2017-11-25

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Device family	Device	Class
Sterile Catheter Connection cables	Sterile Catheter Connection cables	Is
High frequency surgical	FOOT PEDAL	IIb
	SMARTABLATE™ System RF Generator	IIb
	SMARTABLATE™ System Remote Control	IIb
	SMARTABLATE™ System Foot Pedal	IIb
Nerve stimulator	Stimuplex HNS 12	IIa
	Stimpulex® HNS Compact	IIa
Irrigation Pump	SMARTABLATE™ System Irrigation Pump	IIa