



EC-CERTIFICATE

(Full quality assurance system)



This is to certify that the company

Stuckenbrock Medizintechnik GmbH

Lessingstraße 50
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, Implants and surgical instruments, sterile and accessories for HF surgery 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.	285104 MR2
Certificate unique ID	170672846
Effective date	2017-05-13
Expiry date	2022-05-12
Frankfurt am Main	2017-05-13

DQS Medizinprodukte GmbH

Sigrid Uhlemann
Managing Director

Dr. Thomas Feldmann
Head of Certification Body

August-Schanz-Straße 21, 60433 Frankfurt am Main,
Tel. +49 (0) 69 95427-300, medical.devices@dqs-med.de

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
Surgical instruments	Sterile scalpels	IIa
	Sterile blades	IIa
	Guide pins	IIb
	Guide wires	IIb
	Drills	IIa
Accessories for RF surgery units	Handles for HF surgery units	IIb
	Neutral electrodes	IIa
	Active electrodes	IIb
Implants	UHP (prosthesis for wrist joint)	IIb
	Washers	IIb
	Bone plates	IIb
	Bone screws	IIb
	Bone nails	IIb
	Bone clips	IIb
	Bone wires	IIb
	Tantal wire (orthodontic)	IIb
	Finger joint	IIb