EC-CERTIFICATE

(Full quality assurance system)

This is to certify that the company

Helmut Zepf Medizintechnik GmbH

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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:

Skeletal Implants:	Bone Screws (Titan and Implant Steel)	Class IIb
	Bone Pins (Titan)	Class IIb
Torsional ratchet wrenches		Class Im
Trephines		Class IIa

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.	521232 MR2
Certificate unique ID	170714807
Effective date	2019-12-02
Expiry date	2020-10-29
Frankfurt am Main	2019-12-02

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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