

EC-CERTIFICATE

(Full quality assurance system)



This is to certify that the company



Zepf Medical Instruments GmbH

Gunningerstraße 21
78606 Seitingen-Oberflacht
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:

Surgical Instruments and Implants for Osteosynthesis 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.	306732 MR2
Certificate unique ID	170685404
Effective date	2017-06-23
Expiry date	2020-08-23
Frankfurt am Main	2017-06-23

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
Implants for Osteosynthesis from steel and titanium	Bone Nails	IIb
	Bone Plates	IIb
	Bone Screws	IIb
	Bone Wires	IIb
	Osteotomy Staples	IIb
Surgical Instruments	Sterile Disposable Scalpels	IIa
	Sterile Scalpel Blades	IIa
	Suction tubes and cannulas	IIa
	Self-retaining retractors and spreaders	IIa
HF / RF - Instruments	Monopolar Forceps	IIb
	Bipolar Forceps	IIb