EC-CERTIFICATE

(Full quality assurance system)

This is to certify that the company

I.T.S. GmbH

Autal 28
8301 Laßnitzhöhe
Austria

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:

Trauma and orthopedic implants and accessories 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.	070932 MR2
Certificate unique ID	170743212
Effective date	2019-11-14
Expiry date	2024-05-26
Frankfurt am Main	2019-11-14

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
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Device family	Device	Class
Implants	Small Fragment Systems Intramedulary Load Bearing Systems Plate Systems	IIb
Accessories	Rotating instruments	IIa