EC-CERTIFICATE

(Full quality assurance system)

This is to certify that the company

KARL STORZ SE & Co. KG

Dr.-Karl-Storz-Straße 34
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:

Resorbable implants for fixation of soft tissue or bone fragments in joints and Bioresorbable interference screws for ligament reconstruction 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.	528525 MR2
Certificate unique ID	170763442
Effective date	2020-01-18
Expiry date	2022-07-12
Frankfurt am Main	2020-01-18

Digitally signed by Gherman Irina
Date: 2022.03.22 12:35:08 EET
Reason: MoldSign Signature
Location: Moldova

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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
Resorbable implants for fixation of soft tissue or bone fragments in joints	BioPlug suture anchor in the following variants: 2870310 BP BioPlug 3.5 2870411 BP BioPlug 4.2 2870514 BP BioPlug 5.2	III
Bioresorbable interference screws for ligament reconstruction	Mega Fix® in the following variants: Mega Fix® B Mega Fix® C Mega Fix® CP Mega Fix® P	III