CERTIFICATE

This is to certify that the company

Feuerstein GmbH

Gustav-Krone-Straße 3
14167 Berlin
Germany

has implemented and maintains a **Quality Management System**.

Scope:
Development, manufacturing and distribution of needles and needle-suture-combinations for surgery.

Through an audit, documented in a report, performed by DQS Medizinprodukte GmbH, it was verified that the management system fulfills the requirements of the following standard:

DIN EN ISO 13485 : 2016 + AC : 2017-07
EN ISO 13485 : 2016 + AC : 2016
ISO 13485 : 2016

Certificate registration no.	092558 MP2016
Certificate unique ID	170714543
Effective date	2019-01-29
Expiry date	2022-01-28
Frankfurt am Main	2019-01-29

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-16021-01-00

DQS Medizinprodukte GmbH

Sigrid Uhlemann
Managing Director

Dr. Thomas Feldmann
Head of Certification Body
Digitally signed by Iarovoi Petru
Date: 2021.12.16 15:28:56 EET
Reason: MoldSign Signature
Location: Moldova

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

EC-CERTIFICATE

(Full quality assurance system)

This is to certify that the company

Feuerstein GmbH

Gustav-Krone-Straße 3
14167 Berlin
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:

Device	Class
Surgical Sutures (Silk and Polyester) with and without needle	IIa
Surgical Needles steril	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.	092558 MR2
Certificate unique ID	170653076
Effective date	2017-01-20
Expiry date	2022-01-19
Frankfurt am Main	2017-01-20

DQS Medizinprodukte GmbH

Sigrid Uhlemann
Managing Director

Dr. Thomas Feldmann
Head of Certification Body

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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.

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