



## **EC-CERTIFICATE**



(Full quality assurance system)

This is to certify that the company

## **Hermann Medizintechnik GmbH**

Württemberger Straße 26 78567 Fridingen 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:

Instruments and accessories for the invasive and minimally invasive surgery, urology, hysteroscopy, laparoscopy and arthroscopy, endoscopic devices, insufflators, HF surgical devices, titanium implant systems and implants in accordance with the 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. 068177 MR2
Certificate unique ID 170776015
Effective date 2021-02-15
Expiry date 2024-02-18
Frankfurt am Main 2021-02-15

**DQS Medizinprodukte GmbH** 

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Sigrid Uhlemann Managing Director Dr. Thomas Feldmann Head of Certification Body

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**Annex to certificate** 

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## Hermann Medizintechnik GmbH

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Device family	Device	Class
Laparoscopic Instruments	Instruments and accessories for the invasive and minimally invasive surgery, for urology, hysteroscopy, laparoscopy and arthroscopy	lla
Endoscopic Instruments	Arthroscopes, surgical laparoscopes, cystoscopes, adapters, ocular funnels, laparoscopes, endoscopes, nasoscopes/sinuscopes, hysteroscopes	lla
Insufflators	Insufflators	IIb
HF surgical devices	Electrode, HF surgery, active electrode, foot switch controlled	Ilb
HF generators	HF generators as well as instruments for the HF surgery	llb
Titanium implant systems	Maxillofacial, hand and radius	Ilb
Implants	Mandibular, dental, IMF, steel implants for osteosynthesis and orthopedics	Ilb

