



EC-CERTIFICATE

(Full quality assurance system)



This is to certify that the company

Hermann Medizintechnik GmbH

Württembergische 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	170723992
Effective date	2019-02-19
Expiry date	2024-02-18
Frankfurt am Main	2019-02-19

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.



Annex to certificate
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Device family	Device	Class
Instruments and accessories	Instruments and accessories for the invasive and minimally invasive surgery, for urology, hysteroscopy, laparoscopy and arthroscopy	Ila
Endoscopic devices	suction and irrigation pumps	Ila
Insufflators	Insufflators	IIb
HF surgical devices	HF generators as well as instruments for the HF surgery including bipolar instruments	IIb
Titanium implant systems	Maxillofacial, hand and radius	IIb
Implants	Mandibular, dental, IMF, steel implants for osteosynthesis	IIb