



EC-CERTIFICATE

(Full quality assurance system)

DQS Medizinprodukte GmbH

hereby certifies that the company

Günter Bissinger Medizintechnik GmbH

Hans-Theisen-Str. 1
79331 Teningen/Baden
Germany

has implemented and maintains a full quality assurance system which applies to the products at every stage from design to final controls.

An audit, documented in a report, performed by DQS, has verified that this quality assurance system fulfils the requirements of

Annex II – excluding Section 4 of Council Directive 93/42/EEC concerning medical devices

with respect to the following medical devices:

Active and non active medical devices according to annex

The manufacturer is subject to surveillance according to Annex II, Section 5. The CE marking with the Notified Body 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. In case of class Is devices the certificate is restricted to the aspects of manufacture concerned with securing and maintaining sterile conditions. In case of class Im devices the certificate is restricted to the aspects of manufacture concerned with the conformity of the products with metrological requirements.

Certificate registration No.	003171 MR2
Certificate unique ID	170515115
Effective date	2011-04-26
Expiry date	2016-04-25
Frankfurt am Main	2011-04-04

Frank Graichen
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DQS Medizinprodukte GmbH is a Notified Body according to Council Directive 93/42/EEC concerning medical devices with the Notified Body Number 0297.



Annex to Certificate
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Categories of devices:

Surgical and ancillary
surgical equipment:

Non active medical device for
repeated use:

Listed devices:

RF-surgery device
Compact Coagulator 8070 (class IIb)

Bipolar instruments and accessories
for RF-surgery (class IIb)

Monopolar instruments and
accessories for RF-surgery (class IIb)

Bipolar forceps (class III)

Uterine manipulator (class IIa)