



# EC-CERTIFICATE

(Full quality assurance system)



This is to certify that the company



**BHT Hygienetechnik GmbH**

Division

Messerschmittstr. 11  
86368 Gersthofen  
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 family	Device	Class
Disinfection equipment	INNOVA Serie M2 / E2 / E2 CMS INNOVA Serie M2s / E2s / E2s CMS INNOVA Serie M3 / E3 / E3CMS INNOVA Serie M4 / E4 / E4CMS INNOVA Serie M5 / E5 / E5CMS / E5CMS EFF INNOVA Serie 3s INNOVA Serie 4s	IIb

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. 019906 MR2  
Certificate unique ID 170722750  
Effective date 2018-09-22  
Expiry date 2022-07-15  
Frankfurt am Main 2018-09-22

**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.