



EC-CERTIFICATE

(Full quality assurance system)

DQS Medizinprodukte GmbH

hereby certifies that the company

OLYMPUS

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GYRUS MEDICAL GmbH

Gotenstraße 3
78532 Tuttlingen
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:

Endoscopes and Surgical Instruments

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.

Certificate registration no.	019877 MR2
Certification ID	170497412
Date of certification	2010-07-14
Valid until	2015-07-13

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Head of Certification Body

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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
Registration No. 019877 MR2
Certificate ID 170497412
(Issued: 2010-07-14)

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Products	Classification
Surgical Instruments	Drills Polisher Saws Forceps RF surgical-instruments Instruments with suction irrigation Resectoscopes (work elements without electrodes)
Endoscopes	Laryngoscopes Nasoscopes Otosopes Rhinoscopes Bronchoscopes