



EC-CERTIFICATE

(Full quality assurance system)



This is to certify that the company

OASIS® Medical, Inc.

510 – 528 S. Vermont Avenue
Glendora, CA, 91741
United States of America

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:

Ophthalmic devices according to 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.	288050 MR2
Certificate unique ID	170702849
Effective date	2018-09-16
Expiry date	2023-09-15
Frankfurt am Main	2018-09-16

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
Ophthalmic Devices	Lacrimal Plugs	Ilb
	Irrigation / Aspiration Instruments	Ila
	Microsurgical Instruments	Ila
	HPMC Viscoelastics	Ila
	Eye Sponges	Ila
	Corneal Marking Instruments	Is
	Pupillometer	Im
	Iris Expander	Ila
	Punctum Plug Gauges	Im
Collagen Corneal Shield	III	