



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	170772629
Effective date	2020-10-22
Expiry date	2023-09-15
Frankfurt am Main	2020-10-22

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.





Annex to certificate
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Device family	Device	Class
Ophthalmic Devices	SOFT PLUG® Silicone Punctum Plugs	IIb
	SOFT PLUG® Extended Duration Plugs	IIb
	SOFT PLUG® Extended Duration 180 Canalicular Plugs	IIb
	FORM FIT® Hydrogel Canalicular Plugs	IIb
	Disposable Microsurgical Instruments	IIa
	PremierEdge® Microsurgical Knives	IIa
	VISCO SHIELD® HPMC Viscoelastic (8,000 cps and 20,000 cps)	IIa
	VISCO SHIELD® HPMC Viscoelastic Topical (8,000 cps)	Is
	SOFT CELL® PVA Foam Sponge Products	IIa
	SOFT CELL® PVA Foam Surgical Spears	IIa
	Surgical Marking Pen	Is
	OASIS® Iris Expander	IIa
	Lacrimal Instruments	Im
	SOFT SHIELD® Collagen Shields	III
Iris Retractor	IIa	