



510-528 S. VERMONT AVENUE ■ GLENDORA, CA 91741
800.528.9786 ■ 800.631.7210 FAX
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www.oasismedical.com

DECLARATION OF CONFORMITY

Expiration 2021-09-15

MANUFACTURER: OASIS® Medical, Inc.
510-514 South Vermont Avenue
Glendora, CA USA 91741

EUROPEAN REPRESENTATIVE: Donawa Lifescience Consulting Srl
Piazza Albania, 10
00153 Roma, Italy

PRODUCT: Lacrimal Instruments
REF #: See attached sheet

CLASSIFICATION: Class Im, Rule 6.3 according to Annex IX of Directive 93/42/EEC

CONFORMITY ASSESMENT ROUTE: Annex VII of Directive 93/42/EEC

OASIS® MEDICAL, INC. DECLARES THAT THE ABOVE MENTIONED PRODUCTS CONFORM TO THE PROVISIONS OF THE COUNCIL DIRECTIVE 93/42/EEC FOR MEDICAL DEVICES. ALL TECHNICAL DOCUMENTATION IS RETAINED UNDER THE PREMISES OF THE MANUFACTURER.

TO THE BEST OF ITS KNOWLEDGE, INFORMATION AND BELIEF, OASIS® MEDICAL, INC. IS IN COMPLIANCE, IN ALL MATERIAL RESPECTS WITH ITS QUALITY MANAGEMENT SYSTEM ACCORDING TO EN ISO 13485:2016 AND OUR GOOD FAITH UNDERSTANDING OF THE REQUIREMENTS OF THE COUNCIL DIRECTIVE 93/42/EEC. THIS DECLARATION IS ISSUED UNDER THE SOLE RESPONSIBILITY OF OASIS® MEDICAL, INC.

NOTIFIED BODY: DQS 0297 – DQS Medizinprodukte GmbH
August-Schanz-Strasse 21
60433 Frankfurt a.M.
Germany

EC CERTIFICATE(S): EC Certificate Number: 288050 MR2
Issued: 2018-09-16
Valid Until: 2023-09-15

QUALITY MANAGEMENT SYSTEM: EN ISO 13485:2016

CERTIFICATE(S): Certificate Number: 288050 MP2016
Issued: 2018-09-16
Valid Until: 2021-09-15

SIGNATURE:

Wan-Ting Chen
Regulatory Affairs Specialist, OASIS® Medical, Inc.

02/21/2019

Date



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Lacrimal Instruments:

REF 6625	SOFT PLUG® Punctal Plug Gauge, 0.5mm/ 0.6mm
REF 6627	SOFT PLUG® Punctal Plug Gauge, 0.7mm/ 0.8mm
REF 6630	SOFT PLUG® Punctal Plug Gauge Set, 0.5mm/0.6mm and 0.7mm/0.8mm
REF 6640	Castroviejo Lacrimal Dilator, Double End
REF 6643	Jewelers Forceps, Straight #3
REF 6647	Jewelers Forceps, Curved #7
REF 6648	Grooved Forceps

END OF PRODUCT LIST