510-528 S. VERMONT AVENUE • GLENDORA • CA 91741
800.528.9786 • 800.631.7210 FAX
909.305.5400 • 909.305.9987 FAX
www.oasismedical.com

DECLARATION OF CONFORMITY

Expiration 2027-12-31

MANUFACTURER:	OASIS® Medical, Inc. 510-528 S. Vermont Ave. Glendora, CA USA 91741
SRN:	US-MF-000034540
Basic UDI-DI:	08458190FF630336237KB
EUROPEAN REPRESENTATIVE:	Donawa Lifescience Consulting Srl Piazza Albania, 10 00153 Roma, Italy
PRODUCT:	FORM FIT® Hydrogel Canalicular Plug
REF #:	6303, 6303-T, B-6303
INTENDED PURPOSE:	The OASIS FORM FIT® Hydrogel Canalicular Plug is intended to block tear flow through the lacrimal drainage and to improve the signs and symptoms of moderate dry eye in cases where little improvement has been achieved with topical lubrication.
CLASSIFICATION:	Class llb, Rule 5 Sub rule 3 according to Annex IX of Directive 93/42/EEC
CONFORMITY ASSESSMENT ROUTE:	Annex ll of Directive 93/42/EEC

OASIS® MEDICAL, INC. DECLARES THAT THE ABOVE MENTIONED PRODUCTS CONFORM TO THE PROVISIONS OF THE COUNCIL DIRECTIVE 2023/607 AND EU MDR ARTICLE 120 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 REGULATION (EU) 2017/745. 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: 2020-10-22 Valid Until: 2023-09-15

CONFIRMATION LETTER EU 2023-607: Issued: 2023-06-23
(MDD CERTIFICATE EXTENSION GRANTED BY DQS)

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QUALITY MANAGEMENT SYSTEM: EN ISO 13485:2016

CERTIFICATE(S):

Certificate Number:	288050 MP2016
Issued:	2024-09-04
Valid Until:	2027-09-15

SIGNATURE:

11 Sept 2024

Ishan Patil, PhD Date
Director of Regulatory Affairs, OASIS® Medical, Inc.