510-528 S. VERMONT AVENUE ▪ GLENDORA, CA 91741
800.528.9786 ▪ 800.631.7210 FAX
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DECLARATION OF CONFORMITY

Expiration 2021-09-15

MANUFACTURER:	OASIS® Medical, Inc. 510-528 S. Vermont Ave. Glendora, CA USA 91741
EUROPEAN REPRESENTATIVE:	Donawa Lifescience Consulting Srl Piazza Albania, 10 00153 Roma, Italy
PRODUCT:	FORM FIT® Hydrogel Canalicular Plug
REF #:	6303, 6303-T, B-6303
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 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: IshanPatil 09/28/2018

Ishan Patil Date

Regulatory Affairs Specialist, OASIS® Medical, Inc.