



510-528 S. VERMONT AVENUE ■ GLENDORA, CA 91741  
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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:** Collagen Shield  
**REF #:** See attached sheet

**CLASSIFICATION:** Class III, Rule 17 according to Annex IX of Directive 93/42/EEC

**CONFORMITY ASSESSMENT ROUTE:** Annex II 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, AS AMMENDED BY DIRECTIVE 2007/47/EC AND COMMISSION DIRECTIVE 2003/32/EC FOR MEDICAL DEVICES UTILIZING TISSUES OF ANIMAL ORIGIN. 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 DIRECTIVES 93/42/EEC AND 2003/32/EC. 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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**SoftShield® Collagen Corneal Shield:**

REF 7002	SOFT SHIELD® Collagen Shield, QS (Quick Shield)
REF 7012	SOFT SHIELD® Collagen Shield, 12-Hour
REF 7024	SOFT SHIELD® Collagen Shield, 24-Hour
REF 7072	SOFT SHIELD® Collagen Shield, 72-Hour

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**END OF PRODUCT LIST**