



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 2021-09-15

MANUFACTURER: OASIS® Medical, Inc.
510-528 S. Vermont Ave.
Glendora, CA USA 91741

PRODUCT: SOFT PLUG® Collagen Intracanalicular Plug
REF #: See attached sheet

CLASSIFICATION: FDA Product Code LZU, Unclassified

CONFORMITY ASSESSMENT

ROUTE: 21 CFR 820 et. al Quality System Regulations

OASIS® MEDICAL, INC. DECLARES THAT THE ABOVE MENTIONED PRODUCTS CONFORM TO THE PROVISIONS OF THE UNITED STATES FOOD AND DRUG ADMINISTRATION QUALITY SYSTEM REGULATIONS FOR MEDICAL DEVICES. ALL TECHNICAL DOCUMENTATION IS RETAINED UNDER THE PREMISES OF THE MANUFACTURER.

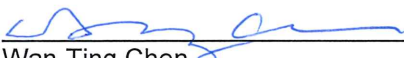
TO THE BEST OF ITS KNOWLEDGE, INFORMATION AND BELIEF, OASIS® MEDICAL, INC. IS IN COMPLIANCE, IN ALL MATERIAL RESPECTS WITH ITS QUALITY MANAGEMENT SYSTEM ACCORDING TO EN ISO 13485:2016 AND OUR GOOD FAITH UNDERSTANDING OF THE REQUIREMENTS OF THE QUALITY SYSTEM REGULATIONS. THIS DECLARATION IS ISSUED UNDER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

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

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



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

SOFT PLUG® Collagen Intracanalicular Plug

REF 6502 SOFT PLUG® Collagen Intracanalicular Plug, 0.2mm DIA x 2mm Long
REF 6503 SOFT PLUG® Collagen Intracanalicular Plug, 0.3mm DIA x 2mm Long
REF 6504 SOFT PLUG® Collagen Intracanalicular Plug, 0.4mm DIA x 2mm Long

Supplied OEM:

REF A12-102 BVI Temporary Collagen Implant [Plug], 0.2mm Dia x 2.0mm Long
REF A12-103 BVI Temporary Collagen Implant [Plug], 0.3mm Dia x 2.0mm Long
REF A12-104 BVI Temporary Collagen Implant [Plug], 0.4mm Dia x 2.0mm Long