

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: 08458190ED64XX36237LK

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

PRODUCT: SOFT PLUG® Extended Duration Plug
REF #: See attached sheet

INTENDED PURPOSE: The SOFT PLUG® Extended Duration Plug is intended for temporary use in patients experiencing dry eye symptoms such as redness, burning, reflex tearing, itching, or foreign body sensations which can be relieved by blockage of the canaliculus.

CLASSIFICATION: Class IIb, Rule 5 Sub rule 3 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 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.

Extended Duration Plugs:

Ref#	Product Name
6400V	SOFT PLUG® Extended Duration Plug, Variety Pack
6402	SOFT PLUG® Extended Duration Plug, 0.2mm DIA X 2mm Long
6402A	SOFT PLUG® Extended Duration Plug, 0.2mm DIA X 2mm Long, 10 Pack
6403	SOFT PLUG® Extended Duration Plug, 0.3mm DIA X 2mm Long
6403A	SOFT PLUG® Extended Duration Plug, 0.3mm DIA X 2mm Long, 10 Pack
6404	SOFT PLUG® Extended Duration Plug, 0.4mm DIA X 2mm Long
6404A	SOFT PLUG® Extended Duration Plug, 0.4mm DIA X 2mm Long, 10 Pack
6405	SOFT PLUG® Extended Duration Plug, 0.5mm DIA X 2mm Long
6405A	SOFT PLUG® Extended Duration Plug, 0.5mm DIA X 2mm Long, 10 Pack

END OF PRODUCT LIST