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 2028-12-31

MANUFACTURER:	OASIS® Medical, Inc. 510-528 S. Vermont Ave. Glendora, CA USA 91741
SRN:	US-MF-000034540
Basic UDI-DI:	08458190IE9XXX46698HY
EUROPEAN REPRESENTATIVE:	Donawa Lifescience Consulting Srl Piazza Albania, 10 00153 Roma, Italy
PRODUCT: **REF #:**	OASIS® Iris Expander 9700, 9700-S, 9625, 9625-S
INTENDED PURPOSE:	The OASIS® Iris Expander is intended to temporarily expand and support the iris in a dilated condition to aid in performing ophthalmic surgery through the pupillary opening.
CLASSIFICATION:	Class lla, Rule 6 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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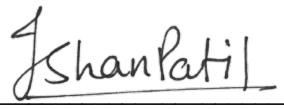
QUALITY MANAGEMENT SYSTEM: EN ISO 13485:2016

CERTIFICATE(S):

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

SIGNATURE:



11 Sept 2024

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