

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: 08458190DI40XX47610LV (Needle)
08458190DI40XX10575K2 (Cannula)
08458190DI40XX47365M7 (Cannula)
08458190DI40XX12319JU (Cannula)
08458190DI40XX47007LA (Cannula)
08458190DI40XX46705M2 (Cystotome)

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

PRODUCT: Disposable Microsurgical Instruments
REF #: See attached sheet

INTENDED PURPOSE: The OASIS Disposable Microsurgical Instruments (Needles) are intended for the delivery of anesthetic to the vicinity of the optic nerve of the eye prior to ocular surgery.

The OASIS Disposable Microsurgical Instruments (Cannulas) are intended for the delivery of air, saline, or anesthetic to the eye; or, for the removal of the lens or remaining cortical material from the eye during ocular surgery.

The OASIS Disposable Microsurgical Instruments (Cystotomes) are intended for cutting the anterior capsule enclosing the lens in a patient's eye during ocular surgery for the removal of the cataractous lens.

CLASSIFICATION: Class IIa, Rule 6 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

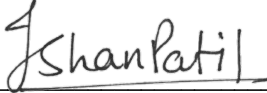
CONFIRMATION LETTER EU 2023-607: Issued: 2023-06-23
(MDD CERTIFICATE EXTENSION GRANTED BY DQS)



QUALITY MANAGEMENT SYSTEM: EN ISO 13485:2016

CERTIFICATE(S): Certificate Number: 288050 MP2016
Issued: 2024-09-04
Valid Until: 2027-09-15

SIGNATURE:


Ishan Patil Date
Director of Regulatory Affairs, OASIS® Medical, Inc. 09 Sept 2024

Disposable Microsurgical Instruments:

Ref #	Product Name
4001, B-4001	Anterior Chamber Cannula, 30g x 7/8" (0.3 x 22mm), 6mm Bend
4001A, B-4001A	Anterior Chamber Cannula, 25g x 7/8" (0.5 x 22mm), 6mm Bend
4001AB, B-4001AB	Anterior Chamber Cannula, 25g x 7/8" (0.5 x 22mm), 10mm Bend
4001AF, B-4001AF	Anterior Chamber Cannula, 25g x 7/8" (0.5 x 22mm), 4mm Bend
4001ATW	Anterior Chamber Cannula, 25g (TW) x 7/8" (0.5 x 22mm), 6mm Bend
4001B	Anterior Chamber Cannula, 23g x 7/8" (0.64 x 22mm), 10mm Bend
4001CF, B-4001CF	Anterior Chamber Cannula, 23g x 7/8" (0.64 x 22mm), 4mm Bend
4001CTW, B-4001CTW	Anterior Chamber Cannula, 23g (TW) x 7/8" (0.64 x 22mm), 8mm Bend
4001D, B-4001D	Irrigating Cannula, 21g x 7/8" (0.4 x 22mm), 4mm Bend
4001F, B-4001F	Anterior Chamber Cannula, 30g x 7/8" (0.3 x 22mm), 4mm Bend
4002, B-4002	Anterior Chamber Cannula, 27g x 7/8" (0.4 x 22mm), 6mm Bend
4002A, B-4002A	Anterior Chamber Cannula, 27g x 7/8" (0.4 x 22mm), 11mm Bend
4002B, B-4002B	Anterior Chamber Cannula, 27g x 7/8" (0.4 x 22mm), 8mm Bend
4002F, B-4002F	Anterior Chamber Cannula, 27g x 7/8" (0.4 x 22mm), 4mm Bend
4002H, B-4002H	Viscoelastic Cannula, 27g x 7/8" (0.4 x 22mm), 8mm Bend
4002L, B-4002L	Anterior Chamber Cannula, 27g x 7/8" (0.4 x 22mm), 9mm Bend
4003	Anterior Chamber Cannula, 25g x 1-1/8", Curved
4003-IK	Lacrimal Irrigation Kit
4004	Retrobulbar Needle (Tri-Facet Point), 25g x 1-1/2" (0.5 x 38mm)
4004B, B-4004B	Retrobulbar Needle (Atkinson Point), 25g x 1-1/2" (0.5 x 38mm)
4004C, B-4004C	Retrobulbar Needle (Atkinson Point), 23g x 1-1/2" (0.64 x 38mm), Thin Wall
4004D, B-4004D	Peribulbar Needle (Atkinson Point), 25g x 7/8" (0.5 x 22mm)
4004F, B-4004F	Peribulbar Needle (Atkinson Point), 23g x 1-1/4" (0.64 x 32mm)
4004H	Anesthesia Needle (Atkinson Point), 27g x 1-1/4"
4004M	Peribulbar Needle (Atkinson Point), 25g x 1-1/4" (0.5 x 32mm)
4005, B-4005	Subtenon Cannula, 19g x 1", Flattened
4005K	Subtenon Cannula, 19g x 1", Flattened, Manufactured for Kestrel Ophthalmics

4005TP	Two-Port Subtenon Anesthesia Cannula, 19g x 1", Curved
4007, B-4007	Simco Double I/A Cannula, 23g x 5/8", Curved
4008, B-4008	Simcoe Cortex Extractor Cannula, 23g x 1/2" (0.64 x 13mm), Curved
4008L, B-4008L	Simcoe Cortex Extractor Cannula, 23g x 7/8" (0.64 x 22mm), Curved
4016	Cortex Extractor Cannula, 21g x .875" (0.875 x 22mm), U-Shaped
4016AH	Hydrodissection Cannula, 25g x 7/8" (0.5 x 22mm), U-Shaped
4016B, B-4016B	Cortex Extractor Cannula, 27g x 7/8" (0.4 x 22mm), U-Shaped
4016F	Cortex Extractor Cannula, 23g x 7/8" (0.64 x 22mm), U-Shaped
4016G, B-4016G	Cortex Extractor Cannula, Micro J-Shaped, 25g x 7/8" (0.5 x 22mm)
4017, B-4017	Irrigating Cystotome, Formed, 25g x 7/8" (0.5 x 22mm)
4017A, B-4017A	Irrigating Cystotome, Straight, 25g x 7/8" (0.5 x 22mm)
4017B, B-4017B	Irrigating Cystotome, Formed, 27g x 7/8", (0.4 x 22mm)
4017G, B-4017G	Irrigating Cystotome, Formed, 25g x 5/8", (0.5 x 16mm)
4017I, B-4017I	Irrigating Cystotome, Formed, 30g x 5/8"
4017IE, B-4017IE	Irrigating Cystotome, Formed, 25g x 5/8", 65° Angle
4017IO, B-4017IO	Irrigating Cystotome, Formed, 27g x 5/8" (0.4 x 16mm)
4017IS, B-4017IS	Irrigating Cystotome, Straight, 27g x 5/8"
4017L, B-4017L	Irrigating Cystotome, 25g x 5/8", Reverse Formed
4017M, B-4017M	Irrigating Cystotome, Angled, 25g x 5/8", (0.5 x 16mm)
4017N, B-4017N	Irrigating Cystotome, Angled, 27g x 5/8", (0.4 x 16mm)
4017R, B-4017R	Capsulorhexis Cystotome, Formed, 27g x 5/8" (0.4 x 16mm), 90° Tip
4017S, B-4017S	Capsulorhexis Cystotome, Formed, 25g x 5/8", 90° Tip
4017X, B-4017X	Irrigating Cystotome, Formed, 25g x 5/8", 1/2" Curve
4017Y	Irrigating Cystotome, (F-SL Curve), 27g x 5/8"
4017Z	Irrigating Cystotome F-SL Curve, 25g x 5/8" (Formed Short Length Curve)
4026, B-4026	Charleux Cannula, 23g x 1/2" (0.64 x 13mm), Curved
4027, B-4027	Kratz Capsule Polisher, 21g x 7/8", 9mm Bend
4027A, B-4027A	Kratz Capsule Polisher, 23g x 7/8" (0.64 x 22mm), 9mm Bend
4027B	Capsule Polisher, 21g x 7/8", 6mm Bend
4027E	Olive Tip Capsule Polisher, 25g x 1", Angled
4027F	Olive Tip Capsule Polisher, 23g x 7/8", Curved
4028, B-4028	Terry Capsule Polisher, 27g x 7/8" (0.4 x 22mm), 6mm Bend
4028B, B-4028B	Capsule Polisher, 23g x 7/8" (0.6 x 22mm), Silicone Sleeve, 7mm Bend
4028D, B-4028D	Capsule Polisher, 27g x 7/8" (0.4 x 22mm), Curved
4029A	Irrigating Vectis, 24g x 5.5mm Wide, 3 Ports
4036, B-4036	A/C Washout Cannula, 19g x 1", 8mm Bend, Flattened
4036A, B-4036A	Hydrodissection Cannula, 25g x 7/8" (0.5 x 22mm), 8mm Bend
4036B, B-4036B	Hydrodissection Cannula, 27g x 7/8" (0.4 x 22mm), 8mm Bend

4036C	Hovis Hydrodissection Cannula, 25g x 7/8" (0.5 x 22mm), 4mm Bend
4036D, B-4036D	Hovis Hydrodissection Cannula, 27g x 7/8" (0.4 x 22mm), 4mm Bend
4036F, B-4036F	Nucleus Hydrodissection Cannula, 25g x 7/8" Helsinki (Curved, Horizontal Flow)
4036FC, B-4036FC	Nucleus Hydrodissection Cannula, 25g x 7/8", Helsinki (Curved, Horizontal Flow), Cranberry Hub
4036G	Nucleus Hydrodissection Cannula, 27g x 7/8" Helsinki (Curved, Horizontal Flow)
4036J, B-4036J	Hydrodissection Cannula (Chang), 27g x 3/4" (0.4 x 19mm), 1mm Bend
4036L	Lin LASIK Cannula, 25g x 7/8", 9mm Bend
4036LB	25g Buratto LASIK Cannula
4036LR, B-4036LR	25g LASIK Irrigator (Lindstrom)
4036LS	26g LASIK Irrigator – Slade
4036M, B-4036M	Nucleus Hydrodissection Cannula, 25g x 7/8" Sauter (Curved, Vertical Flow)
4036N, B-4036N	Nucleus Hydrodissection Cannula, 27g x 7/8" Sauter (Curved, Vertical Flow)
4036P, B-4036P	Cortical Cleaving Hydrodissector, 27g x 7/8" (0.4 x 22mm), 11mm Bend, Round End
4036Q, B-4036Q	Cortical Cleaving Hydrodissector, 27g x 7/8" (0.4 x 22mm), Flat End, 11mm Bend
4042-2S	Infusion Cannula, 20g x 2mm Long
4042-4S	Infusion Cannula, 20g x 4mm Long
4060	Alphachymotrypsin Cannula, 25g x 1-7/8" (0.5 x 48mm), Curved
4068	Kellan Hydrodissection Cannula, 25g x 7/8", Curved
4225	LASIK Irrigator, 6 side Ports
4300P	A/C Maintainer
6005	Lacrimal Cannula, 21g x 1-1/2", Open End, Curved
6006	Lacrimal Cannula, 21g x 1-1/2", Closed End, Straight
6007	Lacrimal Cannula, 25g x 1-1/2", Closed End, Curved
6008	Lacrimal Cannula, 19g/23g x 1-1/2", Straight
6010	Lacrimal Cannula, 26g x 1-1/8", Open End, Curved
BT-4002	Anterior Chamber Irrigation, 27g x 7/8", 6mm Bend
BT-4036A	Hydrodissection Cannula, 25g x 7/8", 8mm Bend
BT-4036D	Hovis Hydrodissection Cannula, 27g x 7/8", 4mm Bend in tray

END OF PRODUCT LIST