



2255 116th Avenue N.E., Bellevue, WA 98004-3039, USA

ISO13485

T: 425-455-5200 or 800-888-6616 · F: 425-462-6669 · E: contact@ocularinc.com · I: www.ocularinc.com

Declaration of Conformity

The European Declaration of Conformity is issued under the sole responsibility of the manufacturer

MANUFACTURER			
Name of Company		Address of Company	
Ocular Instruments, Inc.		2255 116th Ave NE Bellevue, WA 98004 USA	
		Manufacturer SRN	
		US-MF-000007216	
AUTHORIZED REPRESENTATIVE			
Authorized Representative		Address	
Emergo Europe		Westervoortsedijk 60 6827 AT Arnhem The Netherlands	
		AR SRN	
		NL-AR-000000116	
		Telephone/email	
		+31.70.345.8570 EmergoEurope@ul.com	
PRODUCT IDENTIFICATION			
Product Name		Code/Catalog Number	
Diagnostic Lens		See attached	
Intended Purpose		Basic UDI-DI (The Basic UDI-DI has been assigned in accordance with Article 27 of Regulation (EU) 2017/745.)	
Lenses are intended to facilitate a physician's observation of internal ocular structure while placed on the eye by a clinician for ocular examination		06302381262637	
RISK CLASS FOR DEVICES			
Class	Applicable Union Legislation	Other Regulatory References (if applicable)	Common Specifications/Standards
1	Regulation (EU) 2017/745 on medical devices (MDR)	FDA 21 CFR 800 (not applicable to MDR conformity; included for reference only)	ISO 13485:2016, ISO 14971:2019, ISO 10993-1:2018 + AMD1:2020, IEC 62366-1:2015 + AMD1:2020, ISO 15223-1:2021, ASTM D7386
Rule			
5			
NOTIFIED BODY			
Notified Body		Notified Body ID Number	
Not Applicable (Class 1)		Not Applicable (Class 1)	
Route to Compliance		CE Certificate Number	
NA		Not Applicable (Class 1)	

Ocular Instruments, Inc. hereby declares, under its sole responsibility, that the medical devices identified in this Declaration of Conformity (including the product codes listed in the attached pages) conform to Regulation (EU) 2017/745 on medical devices. The devices meet the applicable General Safety and Performance Requirements (GSPRs) of Annex I to Regulation (EU) 2017/745. The manufacturer has established and maintains technical documentation in accordance with Annex II and Annex III to Regulation (EU) 2017/745. This Declaration of Conformity is issued in accordance with Article 19 and Annex IV of Regulation (EU) 2017/745.

Signed for and on behalf of the manufacturer:

Representative: Staci Caldwell

Title Quality Manager

Signature

Place Bellevue, WA USA

Date

09-Feb-26

Declaration of Conformity

The European Declaration of Conformity is issued under the sole responsibility of the manufacturer

Product Code	Long Description	Stock Code	GMDN
O2M	Two Mirror Gonio Diagnostic Lens	5340	11894
O2M-2	Two Mirror Gonio Diagnostic Lens NMR-Kapetensky	791	11894
O2MF	Two Mirror Gonio Diagnostic Lens w/Flange	10747	11894
O4GF	Four Mirror Mini Gonio Diagnostic Lens	5836	11894
O4GF-LR	Four Mirror Mini Gonio Diagnostic Lens w/Large Ring	6327	11894
O4MAC	MaxAC® Four Mirror Gonio Lens w/Small Ring 8.5mm O.D.	7765	11894
O4MAC-15	MaxAC® Four Mirror Gonio Lens w/Small Ring 15mm	9596	11894
O4MAC-17	MaxAC® Four Mirror Gonio Lens w/Small Ring 17mm	9597	11894
O4MAC-1X	MaxAC® 1x Four Mirror Gonio Lens w/ Small Ring 8.5mm O.D.	10577	11894
O4MAC-1X-15	MaxAC® 1x Four Mirror Gonio Lens w/Small Ring 15mm	10613	11894
O4MAC-1X-17	MaxAC® 1x Four Mirror Gonio Lens w/Small Ring 17mm	10614	11894
O4MAC-1X-H	MaxAC® 1x Four Mirror Gonio Lens w/ Handle 8.5mm O.D.	10579	11894
O4MAC-1X-LR	MaxAC® 1x Four Mirror Gonio Lens w/ Large Ring 8.5mm O.D.	10578	11894
O4MAC-1X-LR-15	MaxAC® 1x Four Mirror Gonio Lens w/Large Ring 15mm	10615	11894
O4MAC-1X-LR-17	MaxAC® 1x Four Mirror Gonio Lens w/Large Ring 17mm	10616	11894
O4MAC-H	MaxAC® Four Mirror Gonio Lens w/Handle 8.5mm O.D.	8040	11894
O4MAC-LR	MaxAC® Four Mirror Gonio Lens w/Large Ring 8.5mm O.D.	7795	11894
O4MAC-LR-15	MaxAC® Four Mirror Gonio Lens w/Large Ring 15mm	9598	11894
O4MAC-LR-17	MaxAC® Four Mirror Gonio Lens w/Large Ring 17mm	9599	11894
OACF-15	Three Mirror 15mm Lens Flange Adapter	8952	11894
OACF-17	Three Mirror 17mm Lens Flange Adapter	8953	11894
OACF4-15	Four Mirror 15mm Lens Flange Adapter	9600	11894
OACF4-17	Four Mirror 17mm Lens Flange Adapter	9601	11894
OEMB1	Eye Model Bracket - Single Post	6975	63178
OEMB2	Table Top Eye Model Holder	8084	63178
OEMB3	Eye Model Bracket - Double Post	6976	63178
OEMFK	Eye Model Fill Kit	7109	63178
OEMI-7	Imaging Eye Model	8789	63178
OEMI-KIT	Eye Model Water Fill Kit	12264	63178
OG3M	Three Mirror Universal Gonio Diagnostic Lens 18mm O.D.	822	11894

Declaration of Conformity

The European Declaration of Conformity is issued under the sole responsibility of the manufacturer

OG3M-10	Three Mirror Gonio Diagnostic Lens 10mm O.D	7075	11894
OG3M-13	Three Mirror Small Fissure Gonio Diagnostic Lens 13mm O.D.	680	11894
OG3M-2	Three Mirror Universal Gonio Diagnostic NMR Lens 16mm O.D.	5375	11894
OG3MAC-10	MaxAC® Three Mirror Gonio Lens 10mm O.D	8119	11894
OG3MAC-15	MaxAC® Three Mirror Gonio Lens 15mm O.D.	8958	11894
OG3MAC-17	MaxAC® Three Mirror Gonio Lens 17mm O.D.	8959	11894
OG3MF	Three Mirror Universal Gonio Diagnostic Lens w/Flange 20mm O.D.	823	11894
OG3MHD-10	MaxField® High Definition Three Mirror Gonio Lens 10mm O.D.	9814	11894
OG3MHD-15	MaxField® High Definition Three Mirror Gonio Lens 15mm O.D.	9815	11894
OG3MHD-17	MaxField® High Definition Three Mirror Gonio Lens 17mm O.D.	9816	11894
OG3MI	Three Mirror Gonio Diagnostic Lens 15mm O.D.	826	11894
OG3MP	Three Mirror Gonio Diagnostic Lens 17mm O.D.	825	11894
OG3MS	Three Mirror Small Gonio Diagnostic Lens 18mm O.D.	824	11894
OG3MS-2	Three Mirror Small Gonio Diagnostic Lens NMR 16mm O.D.	5377	11894
OG4MG	Gaasterland Four Mirror Gonio Lens w/Small Ring 8.5mm O.D.	8003	11894
OG4MG-15	Gaasterland Four Mirror Gonio Lens w/Small Ring 15mm O.D.	9614	11894
OG4MG-17	Gaasterland Four Mirror Gonio Lens w/Small Ring 17mm O.D.	9615	11894
OG4MG-1X	Gaasterland 1x Four Mirror Gonio Lens w/Small Ring 8.5mm O.D.	10574	11894
OG4MG-1X-15	Gaasterland 1x Four Mirror Gonio Lens w/Small Ring 15mm O.D.	10609	11894
OG4MG-1X-17	Gaasterland 1x Four Mirror Gonio Lens w/Small Ring 17mm O.D.	10610	11894
OG4MG-1X-H	Gaasterland 1x Four Mirror Gonio Lens w/Handle 8.5mm O.D.	10576	11894
OG4MG-1X-LR	Gaasterland 1x Four Mirror Gonio Lens w/Large Ring 8.5mm O.D.	10575	11894
OG4MG-1X-LR-15	Gaasterland 1x Four Mirror Gonio Lens w/Large Ring 15mm O.D.	10611	11894
OG4MG-1X-LR-17	Gaasterland 1x Four Mirror Gonio Lens w/Large Ring 17mm O.D.	10612	11894
OG4MG-H	Gaasterland Four Mirror Gonio Lens w/Handle 8.5mm O.D.	8093	11894
OG4MG-LR	Gaasterland Four Mirror Gonio Lens w/Large Ring 8.5mm O.D.	8004	11894
OG4MG-LR-15	Gaasterland Four Mirror Gonio Lens w/Large Ring 15mm O.D.	9616	11894
OG4MG-LR-17	Gaasterland Four Mirror Gonio Lens w/Large Ring 17mm O.D.	9617	11894
OGF	Fundus Diagnostic Lens	5200	11894
OGF-2	Fundus Diagnostic Lens NMR	5721	11894
OGP2	Four Mirror Gonioprism 2mm O.D.	7704	11894
OGP2H	Four Mirror Gonioprism w/Handle 2mm O.D.	7705	11894

Declaration of Conformity

The European Declaration of Conformity is issued under the sole responsibility of the manufacturer

OJK	Four Mirror Karickhoff Gonio Diagnostic Lens 18mm O.D.	3198	11894
OJKF	Four Mirror Karickhoff Gonio Diagnostic Lens w/Flange 20mm O.D.	803	11894
OK2MA	Two Mirror Kaufman Laser Lens	7098	11894
OK4DG	Khaw 4D Direct View Gonio Diagnostic Lens	8030	11894
OK4DG-1X	Khaw 1X Direct View Gonio Diagnostic Lens	9868	11894
OKES-12	Koeppe Extra Small Diagnostic Lens 12mm O.D.	697	11894
OKES-14	Koeppe Extra Small Diagnostic Lens 14mm O.D.	4107	11894
OKES-16	Koeppe Extra Small Diagnostic Lens 16mm O.D.	854	11894
OKL	Koeppe Large Diagnostic Lens 19mm O.D.	807	11894
OKM	Koeppe Medium Diagnostic Lens 18mm O.D.	809	11894
OKS	Koeppe Small Diagnostic Lens 17mm O.D.	810	11894
OKWB21	Kapetansky Water Bath 21mm	8517	32758
OLI-1	Layden Infant Gonio Diagnostic Lens 11.5mm O.D.	812	11894
OLI-2	Layden Infant Gonio Diagnostic Lens 10.5mm O.D.	813	11894
OLPR-L	Large Lens Protection Ring	969	11894
OLPR-M	Med Lens Protection Ring	970	11894
OLPR-RIT	Ritch Protection Ring	972	11894
OLPR-S	Small Lens Protection Ring	971	11894
OLPR-SUS (THREA	(THREADED) Sussman Protection Ring	973	11894
OLPR-SUS-2 (THRE	Sussman Protection Ring Large	5172	11894
OPDSG	Posner Diagnostic & Surgical Gonioprism w/Round Handle	817	11894
OPDSG/B	Posner Diagnostic & Surgical Gonioprism w/Round Handle (Blue)	8575	11894
OPDSG/GD	Posner Diagnostic & Surgical Gonioprism w/Round Handle (Gold)	8574	11894
OPDSG/GN	Posner Diagnostic & Surgical Gonioprism w/Round Handle (Green)	8572	11894
OPDSG/P	Posner Diagnostic & Surgical Gonioprism w/Round Handle (Purple)	8573	11894
OPDSG/R	Posner Diagnostic & Surgical Gonioprism w/Round Handle (Red)	8576	11894
OPDSG-2	Posner Diagnostic & Surgical Gonioprism w/Hexagonal Handle	818	11894
OPDSG-2/B	Posner Diagnostic & Surgical Gonioprism w/Hexagonal Handle (Blue)	8580	11894
OPDSG-2/GD	Posner Diagnostic & Surgical Gonioprism w/Hexagonal Handle (Gold)	8579	11894
OPDSG-2/GN	Posner Diagnostic & Surgical Gonioprism w/Hexagonal Handle (Green)	8577	11894
OPDSG-2/P	Posner Diagnostic & Surgical Gonioprism w/Hexagonal Handle (Purple)	8578	11894
OPDSG-2/R	Posner Diagnostic & Surgical Gonioprism w/Hexagonal Handle (Red)	8581	11894

Declaration of Conformity

The European Declaration of Conformity is issued under the sole responsibility of the manufacturer

OPDSG-3	Posner Diagnostic & Surgical Gonioprism w/Ergonomic Handle	6220	11894
OPDSG-3/B	Posner Diagnostic & Surgical Gonioprism w/Ergonomic Handle (Blue)	8585	11894
OPDSG-3/GD	Posner Diagnostic & Surgical Gonioprism w/Ergonomic Handle (Gold)	8584	11894
OPDSG-3/GN	Posner Diagnostic & Surgical Gonioprism w/Ergonomic Handle (Green)	8582	11894
OPDSG-3/P	Posner Diagnostic & Surgical Gonioprism w/Ergonomic Handle (Purple)	8583	11894
OPDSG-3/R	Posner Diagnostic & Surgical Gonioprism w/Ergonomic Handle (Red)	8586	11894
OROCTS	Reichel OCT SteadyEye	11346	11894
OS4M	Sussman Four Mirror Hand Held Gonioscope	863	11894
OS4M/B	Sussman Four Mirror Hand Held Gonioscope (Blue)	8595	11894
OS4M/GD	Sussman Four Mirror Hand Held Gonioscope (Gold)	8594	11894
OS4M/GN	Sussman Four Mirror Hand Held Gonioscope (Green)	8592	11894
OS4M/P	Sussman Four Mirror Hand Held Gonioscope (Purple)	8593	11894
OS4M/R	Sussman Four Mirror Hand Held Gonioscope (Red)	8596	11894
OS4M-2	Sussman Four Mirror Hand Held Gonioscope w/Large Ring	5173	11894
OS4M-2/B	Sussman Four Mirror Hand Held Gonioscope w/Large Ring (Blue)	8590	11894
OS4M-2/GD	Sussman Four Mirror Hand Held Gonioscope w/Large Ring (Gold)	8589	11894
OS4M-2/GN	Sussman Four Mirror Hand Held Gonioscope w/Large Ring (Green)	8587	11894
OS4M-2/P	Sussman Four Mirror Hand Held Gonioscope w/Large Ring (Purple)	8588	11894
OS4M-2/R	Sussman Four Mirror Hand Held Gonioscope w/Large Ring (Red)	8591	11894
OSIE-17	Symons OCT Image Enhancing Lens 17mm O.D.	12349	11894
OSIE-20	Symons OCT Image Enhancing Lens 20mm O.D.	12329	11894
OSMG	Single Mirror Gonio Diagnostic Lens	819	11894
OSMG-2	Single Mirror Gonio Diagnostic Lens NMR-Kapetansky	5871	11894
OSMGF	Single Mirror Gonio Diagnostic Lens w/Flange 17mm O.D.	858	11894
OT4MG	Four Mirror Thorpe Gonio Diagnostic Lens	820	11894
OWSM	Wells Suture Manipulator Lens	10000	11894