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ISO13485

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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	
Laser Lenses		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-2026

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Product Code	Long Description	Stock Code	GMDN
O2MA	Two Mirror Gonio Laser Lens	5344	40238
O2MA-2	Two Mirror Gonio Laser Lens NMR-Kapetensky	790	40238
O2MFA	Two Mirror Gonio Laser Lens w/ Flange	10751	40238
O4GFA	Four Mirror Mini Gonio Laser Lens	5824	40238
O4GFA-LR	Four Mirror Mini Gonio Laser Lens w/Large Ring	6328	40238
OAIA	Abraham Iridectomy Laser Lens	701	40238
OAIY	Abraham Iridectomy Laser Lens	729	40238
OAYA	Abraham Capsulotomy Laser Lens	730	40238
OAYAAC	MaxAC® Capsulotomy Laser Lens	12115	40238
OBWAC	Brasse Wide Field Capsulotomy Lens	12736	40238
OFA1.0	1.0mm Fundus Laser Lens	12100	40238
OFA2.0	2.0mm Fundus Laser Lens	10767	40238
OFA5.4	5.4mm Fundus Laser Lens	7655	40238
OG3MA	Three Mirror Universal Gonio Laser Lens 18mm O.D.	719	40238
OG3MA-13	Three Mirror Small Fissure Gonio Laser Lens 13mm O.D.	681	40238
OG3MA-2	Three Mirror Universal Gonio Laser Lens NMR 16mm O.D.	5374	40238
OG3MFA	Three Mirror Universal Gonio Laser Lens w/Flange 20mm O.D.	720	40238
OG3MFA-SF	Three Mirror Small Fissure Gonio Laser Lens w/Flange 16mm O.D.	7244	40238
OG3MFA-SF-IR	Max360® Three Mirror Small Fissure Lens 16mm O.D.	12221	40238
OG3MIA	Three Mirror Gonio Laser Lens 15mm O.D.	723	40238
OG3MPA	Three Mirror Gonio Laser Lens 17mm O.D.	722	40238
OG3MSA	Three Mirror Small Gonio Laser Lens 18mm O.D.	721	40238
OG3MSA-2	Three Mirror Small Gonio Laser Lens NMR 16mm O.D.	5376	40238
OG3MSA-2-IR	Max360® Three Mirror Universal Gonio Laser Lens 16mm O.D.	11965	40238
OG3MSA-IR	Max360® Three Mirror Universal Gonio Laser Lens 18mm O.D.	11963	40238
OG3MSFA-IR	Max360® Three Mirror Universal Gonio Laser Lens w/ Flange 20mm O.D.	11964	40238
OGFA	Fundus Laser Lens	703	40238
OGFA-2	Fundus Laser Lens NMR	683	40238
OHLSLT	Hwang-Latina 5.0 SLT Gonio Laser Lens	10708	40238
OHLSLTF	Hwang-Latina 5.0 SLT Gonio Laser Lens w/Flange	10716	40238

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OHLSTF-IR	Hwang-Latina 5.0 Indexing SLT Laser Lens w/ Flange	11429	40238
OHLST-IR	Hwang-Latina 5.0 Indexing SLT Laser Lens	11428	40238
OHSA	Hoskins Nylon Suture Laser Lens	705	40238
OJK-2S	Vitreolysis Two Lens Set	11860	40238
OJK-3S	Vitreolysis Three Lens Set	11861	40238
OJKA	Four Mirror Karickhoff Gonio Laser Lens 18mm O.D.	3193	40238
OJKFA	Four Mirror Karickhoff Gonio Laser Lens w/Flange 20mm O.D.	706	40238
OJKPY-25	Karickhoff 25mm Off-Axis Vitreous Laser Lens	8843	40238
OJKPY-30	Karickhoff 30mm Off-Axis Vitreous Laser Lens	10970	40238
OJKY-21	Karickhoff 21mm Vitreous Laser Lens	8836	40238
OKSMA	Single Mirror Kaufman Laser Lens	709	40238
OL1PLTF	Latina 1x Indexing PSLT Gonio Laser Lens	11839	40238
OL5SLT	Latina 5 Bar SLT Gonio Laser Lens	10722	40238
OL5SLTF	Latina 5 Bar SLT Gonio Laser Lens w/Flange	10727	40238
OL5SLTF-IR	Latina 5 Bar Indexing SLT Gonio Laser Lens w/ Flange	11134	40238
OL5SLT-IR	Latina 5 Bar Indexing SLT Gonio Laser Lens	11133	40238
OLSA	Layden Suture Lysis Laser Lens	10651	40238
OLSLT	Latina SLT Gonio Laser Lens	7432	40238
OLSLTF	Latina SLT Gonio Laser Lens w/Flange	9128	40238
OMIC	Mandelkorn Iridotomy-Capsulotomy Laser Lens	5600	40238
OMRA-HM	Mainster High Magnification Laser Lens	699	40238
OMRA-HM-2	Mainster High Magnification Laser Lens NMR	3162	40238
OMRA-PRP-165	Mainster PRP 165 Laser Lens	5803	40238
OMRA-PRP-165-2	Mainster PRP 165 Laser Lens NMR	8098	40238
OMRA-S	Mainster Focal/Grid Laser Lens	760	40238
OMRA-S-2	Mainster Focal/Grid Laser Lens NMR	3160	40238
OMRA-WF	Mainster Wide Field Laser Lens	794	40238
OMRA-WF-2	Mainster Wide Field Laser Lens NMR	3164	40238
OMRA-WFEX	Mainster Wide Field EX	12302	40238
OMSLA	Mandelkorn Suture Lysis Laser Lens	4328	40238
OMV2G	Two Mirror Magna View Gonio Laser Lens	9962	40238
OMV2GF	Two Mirror Magna View Gonio Laser Lens w/Flange	9974	40238

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OMVG200	Goniometric MV200 Laser Lens	11078	40238
OMVG200-2	Goniometric MV200 Laser Lens NMR-Kapetensky	11267	40238
OMVGF200	Goniometric MV200 Laser Lens w/ Flange	11079	40238
OMVGL	Magna View Gonio Laser Lens	5875	40238
OMVGL-1.5X	Magna View 1.5x Gonio Laser Lens	10142	40238
OMVGLF	Magna View Gonio Laser Lens w/Flange	6152	40238
OMVGLF-1.5X	Magna View 1.5x Gonio Laser Lens w/Flange	10155	40238
OMVGLF-IR	Max360® Magna View Gonio Lens W/Flange	11952	40238
OMVGLK-2-IR	Kapetansky Grading Gonio Lens NMR-Kapetensky	12044	40238
OPDT	PDT 1.6x Laser Lens	6619	40238
OPDT-2	PDT 1.6x Laser Lens NMR	9155	40238
OPIG	Pollack Iridotomy-Gonio Laser Lens	7136	40238
OPR-120	ProRetina 120 PB Laser Lens	6237	40238
OPR-120-2	ProRetina 120 PB Laser Lens NMR	9162	40238
OPY-12.5	Peyman Wide Field Yag Laser Lens 12.5mm	732	40238
OPY-18	Peyman Wide Field Yag Laser Lens 18mm	733	40238
OPY-25	Peyman Wide Field Yag Laser Lens 25mm	734	40238
OPYG-12-12	Peyman G. Capsulotomy Yag Laser Lens	735	40238
ORMR-1X	Reichel-Mainster 1x Retina Laser Lens	7195	40238
ORMR-1X-2	Reichel-Mainster 1x Retina Laser Lens NMR	9140	40238
ORMR-1X-P	Pediatric Reichel-Mainster 1x Retina Laser Lens	9772	40238
ORNSA	Ritch Nylon Suture Laser Lens	630	40238
ORTA	Ritch Trabeculoplasty Laser Lens	712	40238
OSMGA	Single Mirror Gonio Laser Lens	716	40238
OSMGA-2	Single Mirror Gonio Laser Lens NMR-Kapetansky	873	40238
OSMGFA	Single Mirror Gonio Laser Lens w/Flange 17mm O.D.	738	40238
OSR230	Staurenghi 230 SLO Retina Lens	7613	40238
OSR230-13	Staurenghi 230 SLO Retina Lens 13mm	9624	40238
OT4MGA	Four Mirror Thorpe Gonio Laser Lens	717	40238
OWISA	Wise Iridotomy-Sphincterotomy Laser Lens	759	40238
OYFA	Yannuzzi Fundus Laser Lens	758	40238