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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	
Indirect 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.)	
Non-contact lenses intended to facilitate a physician's observation of ocular structure, both internal and external, and/or laser therapy.		06302381262739	
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			
1			
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

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Product Code	Long Description	Stock Code	GMDN
OHLA20	HRA 20D Lens Adapter	9090	47946
OI-100M	MaxField® 100D Slit Lamp Indirect Lens	7351	47946
OI-100M/B	MaxField® 100D Slit Lamp Indirect Lens (Blue)	9526	47946
OI-100M/GD	MaxField® 100D Slit Lamp Indirect Lens (Gold)	9525	47946
OI-100M/GN	MaxField® 100D Slit Lamp Indirect Lens (Green)	9523	47946
OI-100M/P	MaxField® 100D Slit Lamp Indirect Lens (Purple)	9524	47946
OI-100M/R	MaxField® 100D Slit Lamp Indirect Lens (Red)	9527	47946
OI-120M	MaxField® 120D Slit Lamp Indirect Lens	6364	47946
OI-120M/B	MaxField® 120D Slit Lamp Indirect Lens (Blue)	9040	47946
OI-120M/GD	MaxField® 120D Slit Lamp Indirect Lens (Gold)	9039	47946
OI-120M/GN	MaxField® 120D Slit Lamp Indirect Lens (Green)	9037	47946
OI-120M/P	MaxField® 120D Slit Lamp Indirect Lens (Purple)	9038	47946
OI-120M/R	MaxField® 120D Slit Lamp Indirect Lens (Red)	9041	47946
OI-14M	MaxField® 14D Binocular Indirect Lens	8741	47946
OI-14M/B	MaxField® 14D Binocular Indirect Lens (Blue)	9214	47946
OI-14M/GD	MaxField® 14D Binocular Indirect Lens (Gold)	9213	47946
OI-14M/GN	MaxField® 14D Binocular Indirect Lens (Green)	9211	47946
OI-14M/P	MaxField® 14D Binocular Indirect Lens (Purple)	9212	47946
OI-14M/R	MaxField® 14D Binocular Indirect Lens (Red)	9215	47946
OI-18M	MaxField® 18D Binocular Indirect Lens	9893	47946
OI-18M/B	MaxField® 18D Binocular Indirect Lens (Blue)	9935	47946
OI-18M/GD	MaxField® 18D Binocular Indirect Lens (Gold)	9934	47946
OI-18M/GN	MaxField® 18D Binocular Indirect Lens (Green)	9932	47946
OI-18M/P	MaxField® 18D Binocular Indirect Lens (Purple)	9933	47946
OI-18M/R	MaxField® 18D Binocular Indirect Lens (Red)	9936	47946
OI-20	MaxLight® 20D Binocular Indirect Lens	657	47946
OI-20/B	MaxLight® 20D Binocular Indirect Lens (Blue)	8238	47946
OI-20/GD	MaxLight® 20D Binocular Indirect Lens (Gold)	8231	47946
OI-20/GN	MaxLight® 20D Binocular Indirect Lens (Green)	8215	47946
OI-20/P	MaxLight® 20D Binocular Indirect Lens (Purple)	8224	47946

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OI-20/R	MaxLight® 20D Binocular Indirect Lens (Red)	8245	47946
OI-20A	MaxAC® 20D Binocular Indirect Lens	7742	47946
OI-20AS	MaxAC® 20D Small Binocular Indirect Lens	11588	47946
OI-20M	MaxField® 20D Binocular Indirect Lens	6836	47946
OI-20M/B	MaxField® 20D Binocular Indirect Lens (Blue)	8162	47946
OI-20M/GD	MaxField® 20D Binocular Indirect Lens (Gold)	8402	47946
OI-20M/GN	MaxField® 20D Binocular Indirect Lens (Green)	8392	47946
OI-20M/P	MaxField® 20D Binocular Indirect Lens (Purple)	8397	47946
OI-20M/R	MaxField® 20D Binocular Indirect Lens (Red)	8163	47946
OI-20MS	MaxField® 20D Small Binocular Indirect Lens	11036	47946
OI-22M	MaxField® 22D Binocular Indirect Lens	8447	47946
OI-22M/B	MaxField® 22D Binocular Indirect Lens (Blue)	9264	47946
OI-22M/GD	MaxField® 22D Binocular Indirect Lens (Gold)	9263	47946
OI-22M/GN	MaxField® 22D Binocular Indirect Lens (Green)	9261	47946
OI-22M/P	MaxField® 22D Binocular Indirect Lens (Purple)	9262	47946
OI-22M/R	MaxField® 22D Binocular Indirect Lens (Red)	9265	47946
OI-25M	MaxField® 25D Binocular Indirect Lens	10504	47946
OI-25M/B	MaxField® 25D Binocular Indirect Lens (Blue)	10508	47946
OI-25M/GD	MaxField® 25D Binocular Indirect Lens (Gold)	10507	47946
OI-25M/GN	MaxField® 25D Binocular Indirect Lens (Green)	10505	47946
OI-25M/P	MaxField® 25D Binocular Indirect Lens (Purple)	10506	47946
OI-25M/R	MaxField® 25D Binocular Indirect Lens (Red)	10509	47946
OI-28	MaxLight® 28D Binocular Indirect Lens	658	47946
OI-28/B	MaxLight® 28D Binocular Indirect Lens (Blue)	9289	47946
OI-28/GD	MaxLight® 28D Binocular Indirect Lens (Gold)	9288	47946
OI-28/GN	MaxLight® 28D Binocular Indirect Lens (Green)	9286	47946
OI-28/P	MaxLight® 28D Binocular Indirect Lens (Purple)	9287	47946
OI-28/R	MaxLight® 28D Binocular Indirect Lens (Red)	9290	47946
OI-28A	MaxAC® 28D Binocular Indirect Lens	7749	47946
OI-28M	MaxField® 28D Binocular Indirect Lens	6837	47946
OI-28M/B	MaxField® 28D Binocular Indirect Lens (Blue)	9326	47946
OI-28M/GD	MaxField® 28D Binocular Indirect Lens (Gold)	9325	47946

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OI-28M/GN	MaxField® 28D Binocular Indirect Lens (Green)	9323	47946
OI-28M/P	MaxField® 28D Binocular Indirect Lens (Purple)	9324	47946
OI-28M/R	MaxField® 28D Binocular Indirect Lens (Red)	9327	47946
OI-30M	MaxField® 30D Binocular Indirect Lens	10439	47946
OI-30M/B	MaxField® 30D Binocular Indirect Lens (Blue)	10443	47946
OI-30M/GD	MaxField® 30D Binocular Indirect Lens (Gold)	10442	47946
OI-30M/GN	MaxField® 30D Binocular Indirect Lens (Green)	10440	47946
OI-30M/P	MaxField® 30D Binocular Indirect Lens (Purple)	10441	47946
OI-30M/R	MaxField® 30D Binocular Indirect Lens (Red)	10444	47946
OI-35M	MaxField® 35D Binocular Indirect Lens	10356	47946
OI-35M/B	MaxField® 35D Binocular Indirect Lens (Blue)	10360	47946
OI-35M/GD	MaxField® 35D Binocular Indirect Lens (Gold)	10359	47946
OI-35M/GN	MaxField® 35D Binocular Indirect Lens (Green)	10357	47946
OI-35M/P	MaxField® 35D Binocular Indirect Lens (Purple)	10358	47946
OI-35M/R	MaxField® 35D Binocular Indirect Lens (Red)	10361	47946
OI-40M	MaxField® 40D Binocular Indirect Lens	10406	47946
OI-40M/B	MaxField® 40D Binocular Indirect Lens (Blue)	10410	47946
OI-40M/GD	MaxField® 40D Binocular Indirect Lens (Gold)	10409	47946
OI-40M/GN	MaxField® 40D Binocular Indirect Lens (Green)	10407	47946
OI-40M/P	MaxField® 40D Binocular Indirect Lens (Purple)	10408	47946
OI-40M/R	MaxField® 40D Binocular Indirect Lens (Red)	10411	47946
OI-54M	MaxField® 54D Slit Lamp Indirect Lens	7014	47946
OI-54M/B	MaxField® 54D Slit Lamp Indirect Lens (Blue)	9401	47946
OI-54M/GD	MaxField® 54D Slit Lamp Indirect Lens (Gold)	9400	47946
OI-54M/GN	MaxField® 54D Slit Lamp Indirect Lens (Green)	9398	47946
OI-54M/P	MaxField® 54D Slit Lamp Indirect Lens (Purple)	9399	47946
OI-54M/R	MaxField® 54D Slit Lamp Indirect Lens (Red)	9402	47946
OI-60M	MaxField® 60D Slit Lamp Indirect Lens	6623	47946
OI-60M/B	MaxField® 60D Slit Lamp Indirect Lens (Blue)	9426	47946
OI-60M/GD	MaxField® 60D Slit Lamp Indirect Lens (Gold)	9425	47946
OI-60M/GN	MaxField® 60D Slit Lamp Indirect Lens (Green)	9423	47946
OI-60M/P	MaxField® 60D Slit Lamp Indirect Lens (Purple)	9424	47946

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OI-60M/R	MaxField® 60D Slit Lamp Indirect Lens (Red)	9427	47946
OI-66M	MaxField® 66D Slit Lamp Indirect Lens	6633	47946
OI-66M/B	MaxField® 66D Slit Lamp Indirect Lens (Blue)	9451	47946
OI-66M/GD	MaxField® 66D Slit Lamp Indirect Lens (Gold)	9450	47946
OI-66M/GN	MaxField® 66D Slit Lamp Indirect Lens (Green)	9448	47946
OI-66M/P	MaxField® 66D Slit Lamp Indirect Lens (Purple)	9449	47946
OI-66M/R	MaxField® 66D Slit Lamp Indirect Lens (Red)	9452	47946
OI-72M	MaxField® 72D Slit Lamp Indirect Lens	7500	47946
OI-72M/B	MaxField® 72D Slit Lamp Indirect Lens (Blue)	9476	47946
OI-72M/GD	MaxField® 72D Slit Lamp Indirect Lens (Gold)	9475	47946
OI-72M/GN	MaxField® 72D Slit Lamp Indirect Lens (Green)	9473	47946
OI-72M/P	MaxField® 72D Slit Lamp Indirect Lens (Purple)	9474	47946
OI-72M/R	MaxField® 72D Slit Lamp Indirect Lens (Red)	9477	47946
OI-78M	Osher Maxfield® 78D Slit Lamp Indirect Lens	4386	47946
OI-78M/B	Osher Maxfield® 78D Slit Lamp Indirect Lens (Blue)	8275	47946
OI-78M/GD	Osher Maxfield® 78D Slit Lamp Indirect Lens (Gold)	8268	47946
OI-78M/GN	Osher Maxfield® 78D Slit Lamp Indirect Lens (Green)	8252	47946
OI-78M/P	Osher Maxfield® 78D Slit Lamp Indirect Lens (Purple)	8261	47946
OI-78M/R	Osher Maxfield® 78D Slit Lamp Indirect Lens (Red)	8282	47946
OI-84M	MaxField® 84D Slit Lamp Indirect Lens	7016	47946
OI-84M/B	MaxField® 84D Slit Lamp Indirect Lens (Blue)	9501	47946
OI-84M/GD	MaxField® 84D Slit Lamp Indirect Lens (Gold)	9500	47946
OI-84M/GN	MaxField® 84D Slit Lamp Indirect Lens (Green)	9498	47946
OI-84M/P	MaxField® 84D Slit Lamp Indirect Lens (Purple)	9499	47946
OI-84M/R	MaxField® 84D Slit Lamp Indirect Lens (Red)	9502	47946
OI-HM	MaxLight® High Mag 78D Slit Lamp Indirect Lens	659	47946
OI-HM/B	MaxLight® High Mag 78D Slit Lamp Indirect Lens (Blue)	8312	47946
OI-HM/GD	MaxLight® High Mag 78D Slit Lamp Indirect Lens (Gold)	8305	47946
OI-HM/GN	MaxLight® High Mag 78D Slit Lamp Indirect Lens (Green)	8289	47946
OI-HM/P	MaxLight® High Mag 78D Slit Lamp Indirect Lens (Purple)	8298	47946
OI-HM/R	MaxLight® High Mag 78D Slit Lamp Indirect Lens (Red)	8319	47946
OI-HM-78M	MaxField® High Mag 78 Slit Lamp Indirect Lens	8465	47946

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OI-HM-78M/B	MaxField® High Mag 78 Slit Lamp Indirect Lens (Blue)	8513	47946
OI-HM-78M/GD	MaxField® High Mag 78 Slit Lamp Indirect Lens (Gold)	8512	47946
OI-HM-78M/GN	MaxField® High Mag 78 Slit Lamp Indirect Lens (Green)	8510	47946
OI-HM-78M/P	MaxField® High Mag 78 Slit Lamp Indirect Lens (Purple)	8511	47946
OI-HM-78M/R	MaxField® High Mag 78 Slit Lamp Indirect Lens (Red)	8514	47946
OI-LROP	Landers ROP Lens Attachment	10064	47946
OI-LSA	MaxAC® Lens Stand	8474	13730
OI-SP	Ultra View Small Pupil Slit Lamp Binocular Indirect Lens	4902	47946
OI-SRG428	Saxena Retinal Grid 428	10058	47946
OI-SRG520	Saxena Retinal Grid 520	9695	47946
OI-ST	Indirect Lens Sterilizing Tray	7568	13730
OI-STD	MaxLight® Standard 90D Slit Lamp Indirect Lens	660	47946
OI-STD/B	MaxLight® Standard 90D Slit Lamp Indirect Lens (Blue)	8201	47946
OI-STD/GD	MaxLight® Standard 90D Slit Lamp Indirect Lens (Gold)	8194	47946
OI-STD/GN	MaxLight® Standard 90D Slit Lamp Indirect Lens (Green)	8179	47946
OI-STD/P	MaxLight® Standard 90D Slit Lamp Indirect Lens (Purple)	8187	47946
OI-STD/R	MaxLight® Standard 90D Slit Lamp Indirect Lens (Red)	8208	47946
OI-STD-LR	MaxLight® Standard 90D Slit Lamp Indirect Lens w/Large Ring	6109	47946
OI-STD-LR/B	MaxLight® Standard 90D Slit Lamp Indirect Lens w/Large Ring (Blue)	8376	47946
OI-STD-LR/GD	MaxLight® Standard 90D Slit Lamp Indirect Lens w/Large Ring (Gold)	8371	47946
OI-STD-LR/GN	MaxLight® Standard 90D Slit Lamp Indirect Lens w/Large Ring (Green)	8361	47946
OI-STD-LR/P	MaxLight® Standard 90D Slit Lamp Indirect Lens w/Large Ring (Purple)	8366	47946
OI-STD-LR/R	MaxLight® Standard 90D Slit Lamp Indirect Lens w/Large Ring (Red)	8381	47946
OI-STDM	MaxField® Standard 90D Slit Lamp Indirect Lens	7015	47946
OI-STDM/B	MaxField® Standard 90D Slit Lamp Indirect Lens (Blue)	8164	47946
OI-STDM/GD	MaxField® Standard 90D Slit Lamp Indirect Lens (Gold)	8423	47946
OI-STDM/GN	MaxField® Standard 90D Slit Lamp Indirect Lens (Green)	8413	47946
OI-STDM/P	MaxField® Standard 90D Slit Lamp Indirect Lens (Purple)	8418	47946
OI-STDM/R	MaxField® Standard 90D Slit Lamp Indirect Lens (Red)	8165	47946
OI-STDM-LR	MaxField® Standard 90D Slit Lamp Indirect Lens w/Large Ring	7017	47946
OI-STDM-LR/B	MaxField® Standard 90D Slit Lamp Indirect Lens w/Large Ring (Blue)	8347	47946
OI-STDM-LR/GD	MaxField® Standard 90D Slit Lamp Indirect Lens w/Large Ring (Gold)	8340	47946

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OI-STDM-LR/GN	MaxField® Standard 90D Slit Lamp Indirect Lens w/Large Ring (Green)	8326	47946
OI-STDM-LR/P	MaxField® Standard 90D Slit Lamp Indirect Lens w/Large Ring (Purple)	8333	47946
OI-STDM-LR/R	MaxField® Standard 90D Slit Lamp Indirect Lens w/Large Ring (Red)	8354	47946
OLCC	Lens Cleaning Cloth	6601	47946