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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	
Surgical 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

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Product Code	Long Description	Stock Code	GMDN
OADVX-H	Ahmed DVX Surgical Gonio Lens W/ Handle	12417	11894
OASG	Ahmed 1.5x Surgical Gonio Lens	11017	11894
OASG-H	Ahmed 1.5x Surgical Gonio Lens w/ Handle	11018	11894
OBVI	Landers Biconcave Vitrectomy Lens w/Infusion Handle	830	58037
OFV-4	Foxman Vitrectomy Lens Ring	10664	32758
OFVI	Flat Vitrectomy Lens w/Infusion Handle	7408	58037
OHBG-1	Hoskins-Barkan Goniectomy Infant Lens 10mm O.D.	832	11894
OHBG-2	Hoskins-Barkan Goniectomy Premature Lens 9mm O.D.	833	11894
OHBG-3	Hoskins-Barkan Goniectomy Adult Lens 11.5 O.D.	799	11894
OHBVE	Biconcave Vitrectomy Lens w/Hexagonal Handle	7944	58037
OHFVE	Flat Vitrectomy Lens w/Hexagonal Handle	7930	58037
OHMVE	Magnifying Vitrectomy Lens w/Hexagonal Handle	7958	58037
OHSO-LH	Hill Surgical Gonioprism (Left-Hand)	8716	11894
OHSO-RH	Hill Surgical Gonioprism (Right-Hand)	8717	11894
OHSOG-LH	Hill Open Access Surgical Gonioprism (Left-Hand)	11854	11894
OHSOG-RH	Hill Open Access Surgical Gonioprism (Right-Hand)	11925	11894
OHWVE	Wide Field Vitrectomy Lens w/Hexagonal Handle	7959	58037
OIV-132	132D Indirect Vitrectomy Lens	7400	58037
OIV-H132	132D Indirect Vitrectomy Lens Holder	7418	58037
OIVS2-HEX	IVS2 Hex Driver	12079	58037
OIVS2-K	Sterilizable Rubber Knob for OIVS2	11242	58037
OIVS2L	Inverter Vitrectomy System For Leica Type Microscopes	11160	58037
OIVS2L-EH	Inverter Vitrectomy System Set For Leica Type Microscopes	11208	58037
OIVS2L-EHNA	Inverter Vitrectomy System Set For Leica Type Microscopes	11211	58037
OIVS2L-WE	Inverter Vitrectomy System Set For Leica Type Microscopes	11223	58037
OIVS2L-WEH	IVS Leica Set W/WF, EQ & HM	11210	58037
OIVS2L-WEHNA	Inverter Vitrectomy System Set For Leica Type Microscopes	11214	58037
OIVS2L-WENA	Inverter Vitrectomy System Set For Leica Type Microscopes	11212	58037
OIVS2L-WH	Inverter Vitrectomy System Set For Leica Type Microscopes	11209	58037
OIVS2L-WHNA	Inverter Vitrectomy System Set For Leica Type Microscopes	11213	58037

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OIVS2L-WW	Inverter Vitrectomy System Set For Leica Type Microscopes	12236	58037
OIVS2Z	Inverter Vitrectomy System For Zeiss Type Microscopes	11159	58037
OIVS2Z-EH	Inverter Vitrectomy System Set For Zeiss Type Microscopes	11215	58037
OIVS2Z-EHNA	Inverter Vitrectomy System Set For Zeiss Type Microscopes	11218	58037
OIVS2Z-WE	Inverter Vitrectomy System Set For Zeiss Type Microscopes	11222	58037
OIVS2Z-WEH	Inverter Vitrectomy System Set For Zeiss Type Microscopes	11217	58037
OIVS2Z-WEHNA	Inverter Vitrectomy System Set For Zeiss Type Microscopes	11221	58037
OIVS2Z-WENA	Inverter Vitrectomy System Set For Zeiss Type Microscopes	11219	58037
OIVS2Z-WH	Inverter Vitrectomy System Set For Zeiss Type Microscopes	11216	58037
OIVS2Z-WHNA	Inverter Vitrectomy System Set For Zeiss Type Microscopes	11220	58037
OIVS2Z-WW	Inverter Vitrectomy System Set For Zeiss Type Microscopes	12233	58037
OIVS-K	IVS Sterilizable Rubber Knob	5609	58037
OIVS-SD	SCREWDRIVER FOR OIVS	7305	58037
OKSG	Khaw Surgical Gonioprism	8480	11894
OLIV-C	Autoclavable Case 2.65 x 1.54 x 1.00	5661	13730
OLIV-EQ-2	Landers Equatorial II Vitrectomy Lens	6473	58037
OLIV-EQNA	Landers NA Equatorial Vitrectomy Lens	6561	58037
OLIV-H	Handle For Vitrectomy Lenses	5665	63411
OLIV-WF	Landers Wide Field Vitrectomy Lens	5579	58037
OLIV-WFNA	Landers NA Wide Field Vitrectomy Lens	6560	58037
OLTA	Luer Tube Assembly for Round Handle	5873	58037
OLTA-2	Luer Tube Assembly Hexagonal Handle	7998	58037
OLTCW	Landers Wide Field Corneal Window	11316	58037
OLV-1	Landers Tall Two Strut Vitrectomy Lens Ring	838	32758
OLV-1-4P	Landers Four Post Vitrectomy Lens Ring	5961	32758
OLV-1-IN	Landers Irrigating Notched Vitrectomy Lens Ring	696	32758
OLV-1-IR	Landers Irrigating Vitrectomy Lens Ring	798	32758
OLV-1S	Landers Silicone Vitrectomy Lens Ring	797	32758
OLV-1-TN	Landers Tall Notched Vitrectomy Lens Ring	5739	32758
OLV-2	Landers Biconcave Vitrectomy Lens	839	58037
OLV-2-HRI	Landers HRI Biconcave Vitrectomy Lens	991	58037
OLV-3	Machemer Magnifying Vitrectomy Lens	840	58037

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OLV-3-HRI	Landers HRI Magnifying Vitrectomy Lens	992	58037
OLV-4	Peyman Wide Field Vitrectomy Lens	841	58037
OLV-4-HRI	Landers HRI Wide Field Vitrectomy Lens	993	58037
OLV-5	Machemer Flat Vitrectomy Lens	842	58037
OLV-5SR	Machemer Flat Vitrectomy Lens w/Silicone Ring	6092	58037
OLV-6	Tolentino 20° Prism Vitrectomy Lens	843	58037
OLV-6-HRI	Landers HRI 20° Prism Vitrectomy Lens	994	58037
OLV-7	Tolentino 30° Prism Vitrectomy Lens	844	58037
OLV-7-HRI	Landers HRI 30° Prism Vitrectomy Lens	995	58037
OLV-8	Landers 50° Prism Lens	865	58037
OLV-9	Woldoff Prismatic Biconcave Vitrectomy Lens	887	58037
OLV-C2	Autoclavable Case 2.65 x 1.54 X .70	4070	13730
OLV-C3	Autoclavable Case 10 Hole	677	13730
OLV-C3-HRI	Autoclavable Case 10 Hole HRI	675	13730
OLV-C4	Autoclavable Case 2.65 x 1.54 x 1.25	7832	13730
OLV-C5	Autoclavable Case 6.0 x 2.5 x .75	10642	13730
OLV-C6	Autoclavable Case 2.5 x 6 x 1.25	10643	13730
OLV-C7	Autoclavable Case 2.65 x 1.54 x 1.75	10644	13730
OLV-C8	Autoclavable Case 6.0 x 10 x 1.5	10764	13730
OLV-FCP	Landers Lens Forceps	997	63411
OLV-OC	Landers Occluder	996	58037
OLVS-HRI	Landers HRI Vitrectomy Lens Set	990	58037
OMUSG	Mori Upright Surgical Gonio Lens	10105	11894
OMVI	Machemer Magnifying Vitrectomy Lens w/Infusion Handle	845	58037
OOSGP	Osher Surgical Gonio/Posterior Pole Lens	4388	11894
OPFVI	Pediatric Flat Vitrectomy Lens w/Infusion Handle	7596	58037
OPGVI	Peyman-Green Fluid Cell Vitrectomy Lens w/Infusion Handle	846	58037
OPV-B	Pediatric Biconcave Vitrectomy Lens	671	58037
OPV-F	Pediatric Flat Vitrectomy Lens	672	58037
OPV-FCP	Pediatric Vitrectomy Lens Forceps	7333	63411
OPVI-3	Peyman III Wide Field Vitrectomy Lens w/Infusion Handle	874	58037
OPV-P	Pediatric Prism Vitrectomy Lens	673	58037

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OPV-R	Pediatric Vitrectomy Lens Ring	4707	32758
OPV-S	Pediatric Vitrectomy Lens Set	670	58037
ORPSG	Ritch Panoramic Surgical Gonioprism Lens	10200	11894
ORVCS	Reichel Viscous Contact System	9712	63411
ORVLH	Reichel Vitrectomy Lens Holder	10273	63411
OSJAG	Swan Jacob Autoclavable Gonioprism	7320	11894
OSJAG8	Swan Jacob Autoclavable Gonioprism 8mm	11247	11894
OSVS	Landers Surgical Viewing System	6896	58037
OSVS-A	Arm Slotted	7275	58037
OSVS-AC	Arm Clamp	7279	58037
OSVS-C	Case Only. OSVS	7282	58037
OSVS-FC	Frame Clamp	7272	58037
OSVS-I132	Landers Surgical Viewing System With OIV 132 Lens and Holder	7575	58037
OSVS-LFF	Link Female/Female	7277	58037
OSVS-LFM	Link Female/Male	7276	58037
OSVS-P	Post	7280	58037
OSVS-SC	Support Collar	7274	58037
OSVS-TS	Knob 1/4 X 1-1/4 T	7273	58037
OSVS-U132-2	Landers Surgical Viewing System w/Peyman-Wessels-Landers Lens	7839	58037
OSVS-W	Wrench 3/8 X 4 Stainless	7281	58037
OUSG-1.3X-H	Upright 1.3x Surgical Gonio Lens w/Handle	12032	11894
OUSG-F	Upright 1.3x Surgical Gonio Flange Cap	12209	11894
OUV-132-2	Peyman-Wessels-Landers 132D Upright Vitrectomy Lens	7836	58037
OUV-H132-2	Peyman-Wessels-Landers 132D Upright Vitrectomy Lens Holder	7841	58037
OWIV-HM	Woldoff High Mag Vitrectomy Lens	6423	58037
OWIV-HMNA	Woldoff NA High Mag Vitrectomy Lens	6562	58037