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ISO13485

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Declaration of Conformity

PRODUCT IDENTIFICATION	
Product name	Model/number
Diagnostic Lenses	For detailed list of model names and numbers, see attached list.

MANUFACTURER		
Name of company	Address	Representative
Ocular Instruments, Inc.	2255 116 th Ave.. NE Bellevue, WA 98004-3039 USA	Raymond Graham

AUTHORIZED REPRESENTATIVE		
Name of company	Address	Telephone/email
Emergo Europe	Prinsessegracht 20 2514 AP, The Hague The Netherlands	Phone: +31.70.345.8570 Fax: +31.70.346.7299 service@emergogroup.com

REGISTRATION INFORMATION	
Notified Body and ID #	CE certificate number
Not Applicable (Class I)	Not Applicable (Class I)

CONFORMITY ASSESSMENT	
Device classification	Route to compliance
Class: 1 Rule: 5	Annex VII of MDD 93/42/EEC Council Directive

OCULAR INSTRUMENTS declares that the above mentioned products meet the provision of the Council Directive 93/42/EEC for Medical Devices.

COMPANY REPRESENTATIVE: Raymond Graham

TITLE: Regulatory Affairs and Director of Engineering & Product Development

SIGNATURE: 

DATE: 14/02/2018

The following products are included in the Diagnostic Lens technical files.

DIAGNOSTIC LENSES

O2M	Two Mirror Gonio
O2MF	Two Mirror Gonio Lens w/flange
O2M-2	NMR-K Two Mirror Gonio
O4GF	Four Mirror Mini Gonio
O4GF-LR	Four Mirror Mini Gonio w/Large Holding Ring
O4MAC	Maxfield® AC Four Mirror Gonio Lens
O4MAC-LR	Maxfield® AC Four Mirror Gonio Lens w/large holding ring
O4MAC-H	Maxfield® AC Four Mirror Gonio Lens w/handle
O4MAC-15	Maxfield® AC Four Mirror Gonio 15mm Flange Lens
O4MAC-17	Maxfield® AC Four Mirror Gonio 17mm Flange Lens
O4MAC-LR-15	Maxfield® AC Four Mirror Gonio Lens w/lg holding ring 15mm Flange
O4MAC-LR-17	Maxfield® AC Four Mirror Gonio Lens w/large holding ring 17mm Flange
O4MAC-1X	Maxfield® AC 1X Four Mirror Gonio Lens
O4MAC-1X-H	Maxfield® AC 1X Four Mirror Gonio w/handle
O4MAC-1X-LR	Maxfield® AC 1X Four Mirror Gonio w/large ring
O4MAC-1X-15	Maxfield® AC 1X Four Mirror Gonio w/15mm flange
O4MAC-1X-17	Maxfield® AC 1X Four Mirror Gonio w/17mm flange
O4MAC-1X-LR-15	Maxfield® AC 1X Four Mirror Gonio large ring w/15mm flange
O4MAC-1X-LR-17	Maxfield® AC 1X Four Mirror Gonio large ring w/17mm flange
OCVF	Calhoun Vision Fundus Lens
13036 RxSight	RxSight .766X Fundus Lens
OCVFS1	Calhoun Lens Set
OGF	Fundus Diagnostic Lens
OGF-2	Fundus Diagnostic Lens; NMR
OG3M	Three Mirror Diagnostic; 18mm OD
OG3M-2	Three Mirror Diagnostic; NMR 16mm OD
OG3M-10	Three Mirror Diagnostic; 10mm OD
OG3M-13	Three Mirror Diagnostic; Small, Fissure, 13mm OD
OG3MAC-10	3 Mirror Autoclavable, 10mm OD
OG3MAC-15	3 Mirror Autoclavable, 15mm OD
OG3MAC-17	3 Mirror Autoclavable, 17mm OD
OG3MHD-10	High Def. Three Mirror; 10mm OD
OG3MHD-15	High Def. Three Mirror; 15mm OD
OG3MHD-17	High Def. Three Mirror; 17mm OD
OG3MF	Three Mirror Universal; w/Flange, 20mm OD
OG3MI	Three Mirror Universal; 15mm OD
OG3MP	Three Mirror Universal; 17mm OD
OG3MS	Three Mirror Universal; Small, 18mm OD
OG3MS-2	Three Mirror Universal; Small NMR, 16mm OD
OG4MG	Gaasterland Four Mirror Gonio Lens
OG4MG-LR	Gaasterland Four Mirror Gonio Lens w/large ring
OG4MG-H	Gaasterland Four Mirror Gonio Lens w/handle
OG4MG-15	Gaasterland Four Mirror Gonio 15mm Flange Lens
OG4MG-17	Gaasterland Four Mirror Gonio 17mm Flange Lens
OG4MG-LR-15	Gaasterland Four Mirror Gonio Lens w/large ring 15mm Flange
OG4MG-LR-17	Gaasterland Four Mirror Gonio Lens w/large ring 17mm Flange
OG4MG-1X	Gaasterland 1X Four Mirror Gonio Lens

Diagnostic Lenses Contd.

OG4MG-1X-LR	Gaasterland 1X Four Mirror Gonio w/large ring
OG4MG-1X-H	Gaasterland 1X Four Mirror Gonio w/handle
OG4MG-1X-15	Gaasterland 1X Four Mirror Gonio w/15mm flange
OG4MG-1X-17	Gaasterland 1X Four Mirror Gonio w/17mm flange
OG4MG-1X-LR-15	Gaasterland 1X Four Mirror Gonio large ring w/15mm flange
OG4MG-1X-LR-17	Gaasterland 1X Four Mirror Gonio large ring w/17mm flange
OJK	Karickhoff; 18mm OD
OK4DG	Khaw Direct View Gonio Lens
OK4DG-1X	Khaw Direct View Gonio Lens
OJKF	Karickhoff; w/Flange, 20mm OD
OKEL	Koeppe; Extra Large, 22.5mm
OKL	Koeppe; Large, 19mm
OKM	Koeppe; Medium, 18mm
OKS	Koeppe; Small, 17mm
OKWB21	Kapetensky Water Bath
OLI-1	Layden Infant Lens 11.50mm
OLI-2	Layden Infant Lens 10.50mm
OPDSG	Posner Gonioprism w/Round Handle
OPDSG/GN, OPDSG/P, OPDSG/GD	Posner Gonioprism, w/rnd handle green/purple/gold/red/blue
OPDSG/R,OPDSG/B	
OPDSG-2	Posner Diagnostic & Surgical Gonioprism w/Octagonal Handle
OPDSG-2/GN, OPDSG-2/P,	Posner Gonioprism, w/oct handle green/purple/gold/red/blue
OPDSG-2/GD, OPDSG-2/R, OPDSG-2/B	
OPDSG-3	Posner Diagnostic & Surgical Gonioprism w/Ergonomic Handle
OPDSG-3/GN, OPDSG-3/P,	Posner Gonio, w/ergo handle green/purple/gold/red/blue
OPDSG-3/GD, OPDSG-3/R, OPDSG-3/B	
OS4M	Sussman Four Mirror Gonioscope
OS4M/GN, OS4M/P, OS4M/B, OS4M/GD,	Sussman 4 Mirror Gonioscope green/purple/blue/gold/red
OS4M/R	
OS4M-2	Sussman Four Mirror Gonioscope w/Lg Holding Ring
OS4M-2/GN, OS4M-2/P, OS4M-2/B,	Sussman 4 Mirror Gonioprism w/lg holding ring green /purple
OS4M-2/GD, OS4M-2/R	/blue /gold /red
OSMG	Single Mirror Gonio
OSMGF	Single Mirror Gonio w/flange
OSIE-17	Symons OCT Image Enhancing Lens 17mm
OSIE-20	Symons OCT Image Enhancing Lens 20mm
OSLO60-2	Lee-Mainster SLO Retina Lens
OSR230	Staurenghi 230 SLO Retina Lens
OSR230-13	Staurenghi 230 SLO 13mm Retina Lens
OSMG-2	NMR-K Single Mirror Gonio
OT4MG	Thorpe Four Mirror Gonio

SPECIAL ORDER LENSES

OHBG-1	Hoskins Barkan Goniotomy Infant Lens; 10mm
OHBG-2	Hoskins Barkan Goniotomy Premature Infant; 9mm
OHBG-3	Hoskins Barkan Goniotomy Adult Lens; 11.5mm