



DECLARATION OF CONFORMITY

11046

MANUFACTURER	Volk Optical Inc. 7893 Enterprise Drive Mentor, Ohio 44060 USA Tel: 800-345-8655
EUROPEAN REPRESENTATIVE	Keeler Limited Clewer Hill Road Windsor SL4 4AA UK Tel: +44(0) 1753 857177
PRODUCT	Product Type: Lens and lens accessories (Class I Devices) Sterile single use lenses (Class Is Devices) Catalog Number: As listed in attachment
CLASSIFICATION	Class I devices, Rule 5 according to Annex IX of the MDD Class I(s) devices, Rule 5 according to Annex IX of the MDD
NOTIFIED BODY	BSI (0086)
We herewith declare the above-mentioned products meet the provisions of the Council Directive 93/42/EEC for Medical Devices. All supporting documentation is retained under the premises of the manufacturer.	
STANDARDS APPLIED	ISO 13485
DIRECTIVES APPLIED	MDD (Council Directive 93/42/EEC)
START OF CE MARKING	June 13, 1998
SIGNATURE	
NAME	DAVID BOYO
POSITION	VP Operations
DATE	10/8/18



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SUPER SERIES SLIT LAMP LENSES (Class I)	
Product Name	Product Code
Super 66® Stereo Fundus	VS66
Super 66® – Blue Ring	VS66-BE
Super 66® – Green Ring	VS66-GN
Super 66® – Purple Ring	VS66-PE
Super 66® – Red Ring	VS66-RD
Super 66® – Gold Ring	VS66-GD
Super 66® – Silver Ring	VS66-SR
SuperField® NC	VSFNC
SuperField® NC – Blue Ring	VSFNC-BE
SuperField® NC – Green Ring	VSFNC-GN
SuperField® NC – Purple Ring	VSFNC-PE
SuperField® NC – Red Ring	VSFNC-RD
SuperField® NC – Gold Ring	VSFNC-GD
SuperField® NC – Silver Ring	VSFNC-SR
SuperPupil® XL	VSPXL
Super Vitreo Fundus®	VSVF
Super Vitreo Fundus® – Blue Ring	VSVF-BE
Super Vitreo Fundus® – Green Ring	VSVF-GN
Super Vitreo Fundus® – Purple Ring	VSVF-PE
Super Vitreo Fundus® – Red Ring	VSVF-RD
Super Vitreo Fundus® – Gold Ring	VSVF-GD
Super Vitreo Fundus® – Silver Ring	VSVF-SR
Digital 1.0X Imaging	VDGTLI
Digital Wide Field®	VDGTLWF
Digital Wide Field® – Black Ring	VDGTLWF-BK
Digital Wide Field® – Green Ring	VDGTLWF-GN
Digital Wide Field® – Purple Ring	VDGTLWF-PE
Digital Wide Field® – Red Ring	VDGTLWF-RD
Digital Wide Field® – Gold Ring	VDGTLWF-GD
Digital Wide Field® – Silver Ring	VDGTLWF-SR
Digital High Mag®	VDGTLHM
Digital High Mag® – Black Ring	VDGTLHM-BK
Digital High Mag® – Green Ring	VDGTLHM-GN
Digital High Mag® – Purple Ring	VDGTLHM-PE
Digital High Mag® – Red Ring	VDGTLHM-RD
Digital High Mag® – Gold Ring	VDGTLHM-GD
Digital High Mag® – Silver Ring	VDGTLHM-SR
CONTACT LASER & DIAGNOSTIC LENSES (Class I)	
Product Name	Product Code
Super Macula® 2.2	VSMAC2.2
Area Centralis	VAC
Area Centralis ANF+	VACANF+
Area Centralis NF	VACNF
Trans Equator®	VTE
Trans Equator® ANF+	VTEANF+
Trans Equator® NF	VTENF
QuadrAspheric®	VQFL
QuadrAspheric® ANF+	VQFLANF+
QuadrAspheric® NF	VQFLNF
Super Quad® 160	VSQUAD160
Super Quad® 160 NF	VSQUAD160NF
High Resolution Wide Field	VHRWF
PDT Lens	VPDT
Equator Plus® ANF+	VEPANF+
Equator Plus® NF	VEPNF
Quad Pediatric	VQPED
Centralis Direct®	VCD



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CONTACT LASER & DIAGNOSTIC LENSES (Class I)	
Product Name	Product Code
ASSY, Offset OSA, WA60L	11046
ASSY, Offset OSA, WA60R	11047
GONIO LENSES (Class I)	
Product Name	Product Code
3-Mirror Gonio Fundus NF	V3MIR
3-Mirror Gonio Fundus ANF+	V3MIRANF+
3-Mirror Gonio Fundus (Uncoated) NF	VU3MIR
3-Mirror Gonio Fundus (Uncoated) ANF+	VU3MIRANF+
G-1 Glass Trabeculum Glass Flange	VG1
G-1 Glass Trabeculum No Flange No Fluid	VG1NF
G-2 Glass Trabeculum Glass Flange	VG2
G-2 Glass Trabeculum No Flange No Fluid	VG2NF
G-3 Glass Gonio Fundus Glass Flange	VG3
G-3 Glass Gonio Fundus No Flange No Fluid	VG3NF
G-3 Glass Gonio Fundus Mini No Flange No Fluid	VG3MININF
G-4 Glass Gonio Glass Flange Fluid	VG4
G-4 Glass Hand Held Gonio (Large Ring) No Flange No Fluid	VG4LNF
G-4 Glass Hand Held Gonio (Small Ring) No Flange No Fluid	VG4SNF
G-4 Glass 2 in 1 Handle Gonio No Flange No Fluid 3.5"	VG4HAN2
G-4 Glass High Mag Gonio Flange (Large Ring)	VG4HM
G-4 Glass High Mag Gonio No Flange (Large Ring) No Fluid	VG4HMLNF
G-4 Glass High Mag Gonio No Flange (Small Ring) No Fluid	VG4HMSNF
G-4 Glass High Mag 2 in 1 Handle Gonio No Flange No Fluid	VG4HMHAN2
G-6 Glass Hand Held Gonio – Large	VG6LNF
G-6 Glass NF 2 in 1 Handle	VG6HAN2
Mini 4 Mirror ANF+	V4MANF+
McCall Selective Laser Trabeculoplasty (SLT)	VMSLT
Selective Laser Trabeculoplasty (SLT)	VSLT
Surgical Gonio	VSGACS
Alcon TVG Surgical Gonio	VTSTVG
SINGLE USE VITRECTOMY LENSES (Class Is)	
Product Name	Product Code
Disposable Direct Image Flat SSV®	VFLATSSVD
Disposable Direct Image Flat Vitrectomy	VFD
Disposable Direct Image Wide Field Vitrectomy	VWFD
Disposable Direct Image 1.5x Magnifying Vitrectomy	VMD
Disposable Direct Image 30° Prism Vitrectomy	V30PD
Disposable Direct Image Biconcave Vitrectomy	VBCD
SINGLE USE CONTACT & LASER DIAGNOSTIC LENSES (Class Is)	
Product Name	Product Code
Capsulotomy Disposable	VCAPSD
Iridotomy Disposable	VIRIDD
SINGLE USE BINOCULAR INDIRECT LENSES (Class Is)	
Product Name	Product Code
Single Use 20D	V20LCD
Single Use 28D	V28LCD
SINGLE USE GONIO LENSES (Class Is)	
Product Name	Product Code
Single Use 4-Mirror Gonio	V4MIRD
Single Use 3-Mirror Gonio	V3MIRD
Single Use SLT	VSLTD
POWER ADAPTERS (Class I)	
Product Code	Product Name
20D – 16D Transformer Adapter	VAD20L-16
20D – 24D Transformer Adapter	VAD20L-24
20D – 28D Transformer Adapter	VAD20L-28
SuperField® NC Minus Power Non-Contact Adapter	VSFMINUS
SuperField® NC Plus Power Non-Contact Adapter	VSFPLUS