



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 BOYD
POSITION	VP Operations
DATE	10/8/18



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BINOCULAR INDIRECT LENSES (Class I)

Product Name	Product Code
14D Large Clear	V14LC
15D Large Clear	V15LC
15D Small Clear	V15SC
20D Large Clear	V20LC
20D – Blue Ring	V20LC-BE
20D – Green Ring	V20LC-GN
20D – Purple Ring	V20LC-PE
20D – Red Ring	V20LC-RD
20D – Gold Ring	V20LC-GD
20D – Silver Ring	V20LC-SR
20D Clear ACS® PermaView	V20LCACSPV
25D Large Clear	V25LC
28D Large Clear	V28LC
28D – Blue Ring	V28LC-BE
28D – Green Ring	V28LC-GN
28D – Purple Ring	V28LC-PE
28D – Red Ring	V28LC-RD
28D – Gold Ring	V28LC-GD
28D – Silver Ring	V28LC-SR
28D Clear ACS® PermaView	V28LCACSPV
30D Large Clear	V30LC
30D Small Clear	V30SC
40D Large Clear	V40LC
Pan Retinal 2.2 Clear	VPRC
Pan Retinal 2.2 – Blue Ring	VPRC-BE
Pan Retinal 2.2 – Green Ring	VPRC-GN
Pan Retinal 2.2 – Purple Ring	VPRC-PE
Pan Retinal 2.2 – Red Ring	VPRC-RD
Pan Retinal 2.2 – Gold Ring	VPRC-GD
Pan Retinal 2.2 – Silver Ring	VPRC-SR
Macula Plus 5.5	VMP5.5
Digital Clear Mag	VDGTLCM
Digital Clear Field	VDGTLCF
Digital Clear Field – Black Ring	VDGTLCF-BK
Digital Clear Field – Green Ring	VDGTLCF-GN
Digital Clear Field – Purple Ring	VDGTLCF-PE
Digital Clear Field – Red Ring	VDGTLCF-RD
Digital Clear Field – Gold Ring	VDGTLCF-GD
Digital Clear Field – Silver Ring	VDGTLCF-SR

CLASSIC SLIT LAMP LENSES (Class I)

Product Name	Product Code
60D Clear	V60C
78D Clear	V78C
78D Clear – Blue Ring	V78C-BE
78D Clear – Green Ring	V78C-GN
78D Clear – Purple Ring	V78C-PE
78D Clear – Red Ring	V78C-RD
78D Clear – Gold Ring	V78C-GD
78D Clear – Silver Ring	V78C-SR
90D Clear	V90C
90D Clear – Blue Ring	V90C-BE
90D Clear – Green Ring	V90C-GN
90D Clear – Purple Ring	V90C-PE
90D Clear – Red Ring	V90C-RD
90D Clear – Gold Ring	V90C-GD
90D Clear – Silver Ring	V90C-SR



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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
Centralis Direct® ANF+	VCDANI+
Iridectomy	VIRID
MagPlus Iridectomy	VMPIRID
Capsulotomy	VCAPS
Fundus	VFUNDUS
Fundus 20MM	VFUNDUS20
Blumenthal Suturelysis	VBSL
HR Centralis	VHRC
Blumenthal Iridotomy	VBIRID
Volk Idrees Mid-Vitreous	VIMV
Volk Singh Mid-Vitreous	VSMV
VITRECTOMY LENSES (Class I)	
Product Name	Product Code
Mini Quad®	VMQVIT
Mini Quad® SSV®	VMQVITSSV
Mini Quad® XL	VMQXLVIT
Mini Quad® XL SSV®	VMQXLVITSSV
Mini Quad® ACS®	VMQVITACS
Mini Quad® XL ACS®	VMQXLVITACS
Mini Quad® SSV® ACS®	VMQVITSSVACS
Mini Quad® XL SSV® ACS®	VMQXLVITSSVACS
Central Retinal	VCRLVIT
Central Retinal SSV®	VCRLVITSSV
Central Retinal ACS®	VCRLVITACS
Central Retinal SSV ACS®	VCRLVITSSVACS
Super Macula®	VSMACVIT
DynaView 156	VDVVIT
Flat SSV® ACS®	VFLATSSVACS
Flat ACS®	VFLATACS
Direct Image High Mag ACS®	VFHMSSVACS
Mini Flat SSV® ACS®	VMFLATSSVACS
15° Prism SSV® ACS®	VPRISMSSVACS
15° Prism ACS®	VP15ACS
30° Prism SSV® ACS®	V30PRISMSSVACS
30° Prism ACS®	VP30ACS
45° Prism SSV® ACS®	V45PRISMSSVACS
45° Prism ACS®	VP45ACS
High Mag ACS®	VHIGHMACS
Mid Field SSV® ACS®	VMFSSVACS
Mid Field ACS®	VMIDFACS
Mid Field 30° Prism ACS®	VMF30PACS
Air Fluid Exchange ACS®	VAFXACS
Air Fluid Exchange SSV® ACS®	VAFXSSVACS
Noncontact Surgical WA	VNCSWA
Assy, NC Lens WA Hinged Pronged	10773
Assy, NC Lens HM Hinged Pronged	10775
HR Direct Bi-concave	VHRDBCACS
HR Direct HM NSR Vit	VHRDHMNSRACS
HR Direct HM Vit	VHRDHMACS
HR Direct 1x Vit	VHRDIXACS
IIR Direct 1x NSR Vit	VHRDIXNSRACS
HR Direct 20Prism Vit	VHRD20PACS
HRX Vit	VHRXVIT
HRX SSV® Vit	VHRXVITSSV
HRX Vit ACS®	VHRXVITACS
IIRX Vit SSV® ACS®	VHRXVITSSVACS



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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



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LID LENS ADAPTERS (Class I)	
Product Name	Product Code
60D Lid Lens Adapter	VLLA60
78D Lid Lens Adapter	VLLA78
90D Lid Lens Adapter - A 20mm	VLLA90A
90D Lid Lens Adapter - B 21.5mm	VLLA90B
SuperField® NC Lid Lens Adapter	VLLASFNC
SuperPupil® XL Lid Lens Adapter	VLLASFXL
Super Vitreo Fundus® Lid Lens Adapter	VLLASVF
CONTACT ADAPTERS (Class I)	
Product Name	Product Code
SuperField® UltraField Contact Adapter	VSFCONUF
SuperField® Ultra Field Contact Adapter ANF+	VSFCONUFANF+
SuperField® High Resolution Contact Adapter	VSFCONHR
SuperField® High Resolution Contact Adapter ANF+	VSFCONHRANF+
Super 66® ANF+ Contact Adapter	VS66CONANF+
SuperPupil® XL Contact Adapter	VSPXLCON
SuperPupil® XL Contact Adapter ANF+	VSPXLCONANF+
LENS ACCESSORIES (Class I)	
Product Name	Product Code
ROLS® Reinverter – Zeiss	VROLS – Z
ROLS® + Reinverter – Zeiss+	VROLS – Z+
ROLS® Reinverter – Leica	VROLS – L
ROLS® Reinverter – Leica (Open Flange)	VROLS – LX
ROLS® Reinverter – Leica+	VROLS – L+
ROLS® Reinverter– Leica+ (Open Flange)	VROLS – LX+
ROLS® Magnet Handle	VROLSMAGHAN
VitreoLens Handle Large	VVITHAN-LG, VVITHAN-MQXL
Volk Steady Mount with Case	VSM
Volk Steady Mount 60D/78D Clip	VSM60/78
Volk Steady Mount with 90D Clip	VSM90
Volk Steady Mount with SuperField NC Clip	VSMASFNC
Volk Steady Mount for VSFNC, V90, & V60/78	VSMCLIPSET
60D & 78D Steady Mount Clip	VCLIP60/78
90D Steady Mount Clip	VCLIP90
SuperField® NC Steady Mount Clip	VCLIPSFNC
Suture Ring	VSRS2
Lens Forceps	VLFF
Volk Sterilization Case Small	VSCA
Volk Sterilization Case Large	VSCB
Volk iNview - for iPod Touch	VINVIEW-TCH
Volk iNview - for iPhone 5s	VINVIEW-5S
Volk iNview - for iPhone 6	VINVIEW-6
Volk iNview - Touch Cam	VINVIEWC-TCH