



Declaration of Conformity

MANUFACTURER	Volk Optical Inc. 7893 Enterprise Drive Mentor, Ohio 44060 USA Tel: 800-345-8655
EUROPEAN REPRESENTATIVE	Rudolf Riester GmbH Bruckstraße 31 72417 Jungingen Germany Tel: (+49) 7477-9270-0 Fax: (+49) 7477-9270-70 info@riester.de www.riester.de
PRODUCT	Product Type: Lens and lens accessories (Class I Devices) Sterile single use lenses (Class Is Devices)
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 (2797)
We herewith declare that 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 13485:2016
DIRECTIVES APPLIED	MDD (Council Directive 93/42/EEC)
START OF CE MARKING	June 13, 1998
SIGNATURE	
NAME	GARY WEBER
POSITION	VP FINANCE
DATE	09/20/2019



Declaration of Conformity

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 – Custom Color Ring	V20LC-CC
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



Declaration of Conformity

CLASSIC SLIT LAMP LENSES (Class I)	
Product Name	Product Code
78D Clear – Silver Ring	V78C-SR
78D Clear – Custom Color Ring	V78C-CC
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
90D Clear – Custom Color Ring	V90C-CC
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
Super Field° NC	VSFNC
Super Field° NC – Blue Ring	VSFNC-BE
Super Field° NC – Green Ring	VSFNC-GN
Super Field° NC – Purple Ring	VSFNC-PE
Super Field° NC – Red Ring	VSFNC-RD
Super Field° NC – Gold Ring	VSFNC-GD
Super Field° NC – Silver Ring	VSFNC-SR
Super Pupil° XL	VSPXL
Super Vitreo Fundus°	VSVF
Digital 1.0X Imaging	VDGTL1
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 NF	VACNF
Area Centralis ANF+	VACANF+



Declaration of Conformity

CONTACT LASER & DIAGNOSTIC LENSES (Class I)	
Product Name	Product Code
Trans Equator®	VTE
Trans Equator® NF	VTENF
Trans Equator® ANF+	VTEANF+
QuadrAspheric®	VQFL
QuadrAspheric® NF	VQFLNF
QuadrAspheric® ANF+	VQFLANF+
Super Quad® 160	VSQUAD160
Super Quad® 160 NF	VSQUAD160NF
High Resolution Wide Field	VHRWF
PDT Lens	VPDT
Equator Plus® NF	VEPNF
Equator Plus® ANF+	VEPANF+
Quad Pediatric	VQPED
Centralis Direct®	VCD
Centralis Direct® ANF+	VCDANF+
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® SSV® ACS®	VMQVITSSVACS
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
Direct Image High Mag ACS®	VFHMSSVACS
15° Prism SSV® ACS®	VPRISMSSVACS
30° Prism SSV® ACS®	V30PRISMSSVACS
45° Prism SSV® ACS®	V45PRISMSSVACS
Mid Field SSV® ACS®	VMFSSVACS
Air Fluid Exchange SSV® ACS®	VAFXSSVACS
Assy, NC Lens WA Hinged Pronged	10773
Assy, NC Lens HM Hinged Pronged	10775
HR Direct Bi-concave	VHRDBCACS



Declaration of Conformity

VITRECTOMY LENSES (Class I)	
Product Name	Product Code
HR Direct HM NSR Vit	VHRDHMNSRACS
HR Direct HM Vit	VHRDHMACS
HR Direct 1x Vit	VHRD1XACS
HR Direct 1x NSR Vit	VHRD1XNSRACS
HR Direct 20° Prism Vit	VHRD20PACS
HRX Vit	VHRXVIT
HRX SSV® Vit	VHRXVITSSV
HRX Vit ACS®	VHRXVITACS
HRX Vit SSV® ACS®	VHRXVITSSVACS
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+
Rapid Selective Laser Trabeculoplasty (SLT)	VMSLT
Selective Laser Trabeculoplasty (SLT)	VSLT
Surgical Gonio	VSGACS
Alcon Vold TVG Surgical Gonio	VTSTVG
Volk Vold Surgical Gonio	VTSVVG
SINGLE USE VITRECTOMY LENSES (Class Is)	
Product Name	Product Code
Single Use Direct Image Flat SSV®	VFLATSSVD
Single Use Direct Image Flat SSV®, Box of 10	VFLATSSVD10
Single Use Direct Image Flat SSV®, Box of 100	VFLATSSVD100
Single Use Direct Image Flat SSV®, Box of 800	VFLATSSVD800
Single Use Direct Image Flat	VFD
Single Use Direct Image Flat, Box of 10	VFD10
Single Use Direct Image Flat, Box of 100	VFD100



Declaration of Conformity

SINGLE USE VITRECTOMY LENSES (Class Is)	
Product Name	Product Code
Single Use Direct Image Flat, Box of 800	VFD800
Single Use Direct Image WideField	VWFD
Single Use Direct Image WideField, Box of 10	VWFD10
Single Use Direct Image WideField, Box of 100	VWFD100
Single Use Direct Image WideField, Box of 800	VWFD800
Single Use Direct Image 1.5x Mag	VMD
Single Use Direct Image 1.5x Mag, Box of 10	VMD10
Single Use Direct Image 1.5x Mag, Box of 100	VMD100
Single Use Direct Image 1.5x Mag, Box of 800	VMD800
Single Use Direct Image 30° Prism	V30PD
Single Use Direct Image 30° Prism, Box of 10	V30PD10
Single Use Direct Image 30° Prism, Box of 100	V30PD100
Single Use Direct Image 30° Prism, Box of 800	V30PD800
Single Use Direct Image Biconcave	VBCD
Single Use Direct Image Biconcave, Box of 10	VBCD10
Single Use Direct Image Biconcave, Box of 100	VBCD100
Single Use Direct Image Biconcave, Box of 800	VBCD800
SINGLE USE CONTACT & LASER DIAGNOSTIC LENSES (Class Is)	
Product Name	Product Code
Single Use Capsulotomy	VCAPSD
Single Use Capsulotomy, Box of 10	VCAPSD10
Single Use Capsulotomy, Box of 100	VCAPSD100
Single Use Capsulotomy, Box of 400	VCAPSD400
Single Use Iridotomy	VIRIDD
Single Use Iridotomy, Box of 10	VIRIDD10
Single Use Iridotomy, Box of 100	VIRIDD100
Single Use Iridotomy, Box of 400	VIRIDD400
SINGLE USE BINOCULAR INDIRECT LENSES (Class Is)	
Product Name	Product Code
Single Use 20D	V20LCD
Single Use 20D, Box of 10	V20LCD10
Single Use 20D, Box of 100	V20LCD100
Single Use 20D, Box of 400	V20LCD400
Single Use 28D	V28LCD
Single Use 28D, Box of 10	V28LCD10
Single Use 28D, Box of 100	V28LCD100
Single Use 28D, Box of 400	V28LCD400
SINGLE USE GONIO LENSES (Class Is)	
Product Name	Product Code
Single Use 3-Mirror Gonio	V3MIRD
Single Use 3-Mirror Gonio, Box of 10	V3MIRD10
Single Use 3-Mirror Gonio, Box of 100	V3MIRD100
Single Use 3-Mirror Gonio, Box of 400	V3MIRD400
Single Use 4-Mirror Gonio	V4MIRD
Single Use 4-Mirror Gonio, Box of 10	V4MIRD10
Single Use 4-Mirror Gonio, Box of 100	V4MIRD100
Single Use 4-Mirror Gonio, Box of 400	V4MIRD400



Declaration of Conformity

SINGLE USE GONIO LENSES (Class Is)	
Product Name	Product Code
Single Use SLT	VSLTD
Single Use SLT, Box of 10	VSLTD10
Single Use SLT, Box of 100	VSLTD100
Single Use SLT, Box of 400	VSLTD400
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
Super Field® NC Minus Power Non-Contact Adapter	VSFMINUS
Super Field® NC Plus Power Non-Contact Adapter	VSFPLUS
LID LENS ADAPTERS (Class I)	
Product Name	Product Code
90D Lid Lens Adapter - A 20mm	VLLA90A
90D Lid Lens Adapter - B 21.5mm	VLLA90B
Super Pupil® XL Lid Lens Adapter	VLLASPLX
Super Vitreo Fundus® Lid Lens Adapter	VLLASVF
CONTACT ADAPTERS (Class I)	
Product Name	Product Code
Super Field® UltraField Contact Adapter	VSFCONUF
Super Field® UltraField Contact Adapter ANF+	VSFCONUFANF+
Super Field® High Resolution Contact Adapter	VSFCONHR
Super Field® High Resolution Contact Adapter ANF+	VSFCONHRANF+
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 Long	VVITHAN-LG
VitreoLens Handle for MQXL	VVITHAN-MQXL
Volk Infusion Handle	VINFHAN
Volk Steady Mount with Case	VSM
Volk Steady Mount for VSFNC, V90, & V60/78	VSMCLIPSET
60D & 78D Steady Mount Clip	VCLIP60/78
90D Steady Mount Clip	VCLIP90
Super Field® NC Steady Mount Clip	VCLIPSFNC
Suture Ring	VSR52
Lens Forceps	VLF
Volk Sterilization Case Small	VSCA
Volk Sterilization Case Large	VSCB
INVIEW RETINAL CAMERA & ACCESSORIES (Class I)	
Product Name	Product Code
Volk iNview for iPhone 6	VINVIEW-6
Volk iNview for iPhone 5s	VINVIEW-5S
Volk iNview for iPod Touch	VINVIEW-TCH



Declaration of Conformity

INVIEW RETINAL CAMERA & ACCESSORIES (Class I)	
Product Name	Product Code
Volk iNview Touch Camera	VINVIEWC-TCH
Volk iNview Case	VINVIEW-CASE
Adapter Kit for iNview - iPhone 6	VINVIEWADPT-6
Adapter Kit for iNview - iPhone 5s	VINVIEWADPT-5S
Adapter Kit for iNview – iPod Touch	VINVIEWADPT-TCH