




## Declaration of Conformity

<b>MANUFACTURER</b>	Volk Optical Inc. 7893 Enterprise Drive Mentor, Ohio 44060 USA Tel: 800-345-8655
<b>EUROPEAN REPRESENTATIVE</b>	Rudolf Riester GmbH Bruckstraße 31 72417 Jungingen Germany Tel: (+49) 7477-9270-0 Fax: (+49) 7477-9270-70 info@riester.de www.riester.de
<b>PRODUCT</b>	Product Type: Lenses and lens accessories, iNview & VistaView (Class I Devices) Sterile single use lenses (Class Is Devices)
<b>CLASSIFICATION</b>	Class I Lenses, Accessories & iNview, Rule 1 according to Annex IX of the MDD Class I VistaView, Rule 12 according to Annex IX of the MDD Class I(s) devices, Rule 1 according to Annex IX of the MDD
<b>NOTIFIED BODY</b>	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.	
<b>STANDARDS APPLIED</b>	ISO 13485:2016
<b>DIRECTIVES APPLIED</b>	MDD (Council Directive 93/42/EEC)
<b>START OF CE MARKING</b>	June 13, 1998
<b>SIGNATURE</b>	
<b>NAME</b>	Peter Chen
<b>POSITION</b>	Chief Financial and Operating Officer
<b>DATE</b>	August 18, 2020



## Declaration of Conformity

BINOCULAR INDIRECT LENSES (Class I)	
Product Name	Product Code
14D Large Clear	V14LC
15D Large Clear	V15LC
20D Large Clear	V20LC
20D – Blue Ring	V20LC-BE
20D – Gold Ring	V20LC-GD
20D – Green Ring	V20LC-GN
20D – Purple Ring	V20LC-PE
20D – Red Ring	V20LC-RD
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 – Gold Ring	V28LC-GD
28D – Green Ring	V28LC-GN
28D – Purple Ring	V28LC-PE
28D – Red Ring	V28LC-RD
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 – Gold Ring	VPRC-GD
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 – Silver Ring	VPRC-SR
Macula Plus 5.5	VMP5.5
Digital Clear Field	VDGTLCF
Digital Clear Field – Black Ring	VDGTLCF-BK
Digital Clear Field – Gold Ring	VDGTLCF-GD
Digital Clear Field – Green Ring	VDGTLCF-GN
Digital Clear Field – Purple Ring	VDGTLCF-PE
Digital Clear Field – Red Ring	VDGTLCF-RD
Digital Clear Field – Silver Ring	VDGTLCF-SR
Digital Clear Mag	VDGTLCM
Silver 20D	VSLV20
Silver 28D	VSLV28
20D Cielo	C20
28D Cielo	C28
CLASSIC SLIT LAMP LENSES (Class I)	
Product Name	Product Code
60D Clear	V60C
78D Clear	V78C
78D Clear – Blue Ring	V78C-BE
78D Clear – Gold Ring	V78C-GD



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CLASSIC SLIT LAMP LENSES (Class I)	
Product Name	Product Code
78D Clear – Green Ring	V78C-GN
78D Clear – Purple Ring	V78C-PE
78D Clear – Red Ring	V78C-RD
78D Clear – Silver Ring	V78C-SR
78D Clear – Custom Color Ring	V78C-CC
90D Clear	V90C
90D Clear – Blue Ring	V90C-BE
90D Clear – Gold Ring	V90C-GD
90D Clear – Green Ring	V90C-GN
90D Clear – Purple Ring	V90C-PE
90D Clear – Red Ring	V90C-RD
90D Clear – Silver Ring	V90C-SR
90D Clear – Custom Color Ring	V90C-CC
Silver 78D	VSLV78
Silver 90D	VSLV90
78D Cielo	C78
90D Cielo	C90
SUPER SERIES SLIT LAMP LENSES (Class I)	
Product Name	Product Code
Super 66° Stereo Fundus	VS66
Super 66° – Blue Ring	VS66-BE
Super 66° – Gold Ring	VS66-GD
Super 66° – Green Ring	VS66-GN
Super 66° – Purple Ring	VS66-PE
Super 66° – Red Ring	VS66-RD
Super 66° – Silver Ring	VS66-SR
Super Field° NC	VSFNC
Super Field° NC – Blue Ring	VSFNC-BE
Super Field° NC – Gold Ring	VSFNC-GD
Super Field° NC – Green Ring	VSFNC-GN
Super Field° NC – Purple Ring	VSFNC-PE
Super Field° NC – Red Ring	VSFNC-RD
Super Field° NC – Silver Ring	VSFNC-SR
Super Vitreo Fundus°	VSVF
Super Pupil° XL	VSPXL
Digital 1.0X Imaging	VDGTL1
Digital Wide Field°	VDGTLWF
Digital Wide Field° – Black Ring	VDGTLWF-BK
Digital Wide Field° – Gold Ring	VDGTLWF-GD
Digital Wide Field° – Green Ring	VDGTLWF-GN
Digital Wide Field° – Purple Ring	VDGTLWF-PE
Digital Wide Field° – Red Ring	VDGTLWF-RD
Digital Wide Field° – Silver Ring	VDGTLWF-SR
Digital High Mag°	VDGTLHM
Digital High Mag° – Black Ring	VDGTLHM-BK
Digital High Mag° – Gold Ring	VDGTLHM-GD
Digital High Mag° – Green Ring	VDGTLHM-GN
Digital High Mag° – Purple Ring	VDGTLHM-PE
Digital High Mag° – Red Ring	VDGTLHM-RD



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SUPER SERIES SLIT LAMP LENSES (Class I)	
Product Name	Product Code
Digital High Mag® – Silver Ring	VDGTLHM-SR
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+
Selective Laser Trabeculoplasty (SLT)	VSLT
Rapid SLT	VMSLT
Surgical Gonio	VSGACS
Alcon Vold TVG Surgical Gonio	VTSTVG
Volk Vold Surgical Gonio	VTSVVG
CONTACT LASER & DIAGNOSTIC LENSES (Class I)	
Product Name	Product Code
Area Centralis	VAC
Area Centralis NF	VACNF
Area Centralis ANF+	VACANF+
Equator Plus® NF	VEPNF
Equator Plus® ANF+	VEPANF+
HR Centralis	VHRC
High Resolution Wide Field	VHRWF
PDT Lens	VPDT
Quad Pediatric	VQPED
QuadrAspheric®	VQFL
QuadrAspheric® NF	VQFLNF
QuadrAspheric® ANF+	VQFLANF+
Super Macula® 2.2	VSMAC2.2
Super Quad® 160	VSQUAD160
Super Quad® 160 NF	VSQUAD160NF
Trans Equator®	VTE
Trans Equator® NF	VTENF



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CONTACT LASER & DIAGNOSTIC LENSES (Class I)	
Product Name	Product Code
Trans Equator <sup>®</sup> ANF+	VTEANF+
Capsulotomy	VCAPS
Centralis Direct <sup>®</sup>	VCD
Centralis Direct <sup>®</sup> ANF+	VCDANF+
Fundus	VFUNDUS
Fundus 20MM	VFUNDUS20
Iridectomy	VIRID
MagPlus Iridectomy	VMPIRID
Blumenthal Iridotomy	VBIRID
Blumenthal Suturelysis	VBSL
Volk Idrees Mid-Vitreous	VIMV
Volk Singh Mid-Vitreous	VSMV
VITRECTOMY LENSES (Class I)	
Product Name	Product Code
Central Retinal	VCRLVIT
Central Retinal SSV <sup>®</sup>	VCRLVITSSV
DynaView 156	VDVVIT
HRX Vit	VHRXVIT
HRX SSV <sup>®</sup> Vit	VHRXVITSSV
Mini Quad <sup>®</sup>	VMQVIT
Mini Quad <sup>®</sup> SSV <sup>®</sup>	VMQVITSSV
Mini Quad <sup>®</sup> XL	VMQXLVIT
Mini Quad <sup>®</sup> XL SSV <sup>®</sup>	VMQXLVITSSV
Super Macula <sup>®</sup>	VSMACVIT
Mini Quad <sup>®</sup> ACS <sup>®</sup>	VMQVITACS
Mini Quad <sup>®</sup> SSV <sup>®</sup> ACS <sup>®</sup>	VMQVITSSVACS
Central Retinal ACS <sup>®</sup>	VCRLVITACS
Central Retinal SSV ACS <sup>®</sup>	VCRLVITSSVACS
HRX Vit ACS <sup>®</sup>	VHRXVITACS
HRX Vit SSV <sup>®</sup> ACS <sup>®</sup>	VHRXVITSSVACS
HR Direct 1x Vit	VHRD1XACS
HR Direct 1x NSR Vit	VHRD1XNSRACS
HR Direct Bi-concave	VHRDBCACS
HR Direct HM Vit	VHRDHMACS
HR Direct HM NSR Vit	VHRDHMNSRACS
HR Direct 20° Prism Vit	VHRD20PACS
15° Prism SSV <sup>®</sup> ACS <sup>®</sup>	VPRISMSSVACS
30° Prism SSV <sup>®</sup> ACS <sup>®</sup>	V30PRISMSSVACS
45° Prism SSV <sup>®</sup> ACS <sup>®</sup>	V45PRISMSSVACS
Air Fluid Exchange SSV <sup>®</sup> ACS <sup>®</sup>	VAFXSSVACS
Flat SSV <sup>®</sup> ACS <sup>®</sup>	VFLATSSVACS
Direct Image High Mag ACS <sup>®</sup>	VFHMSSVACS
Mid Field SSV <sup>®</sup> ACS <sup>®</sup>	VMFSSVACS
Assy, NC Lens WA Hinged Pronged	10773
Assy, NC Lens HM Hinged Pronged	10775
SINGLE USE VITRECTOMY LENSES (Class Is)	
Product Name	Product Code
Single Use Direct Image Flat SSV <sup>®</sup>	VFLATSSVD
Single Use Direct Image Flat SSV <sup>®</sup> , Box of 10	VFLATSSVD10



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SINGLE USE VITRECTOMY LENSES (Class Is)	
Product Name	Product Code
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
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 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
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
SINGLE USE BINOCULAR INDIRECT LENSES (Class Is)	
Product Name	Product Code
Single Use 20D	V20LCD



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SINGLE USE BINOCULAR INDIRECT LENSES (Class Is)	
Product Name	Product Code
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
INVIEW RETINAL CAMERA & ACCESSORIES (Class I)	
Product Name	Product Code
Volk iNview for iPhone 5s	VINVIEW-5S
Volk iNview for iPhone 6	VINVIEW-6
Volk iNview for iPod Touch	VINVIEW-TCH
Volk iNview Touch Camera	VINVIEWC-TCH
Adapter Kit for iNview - iPhone 5s	VINVIEWADPT-5S
Adapter Kit for iNview - iPhone 6	VINVIEWADPT-6
Adapter Kit for iNview – iPod Touch	VINVIEWADPT-TCH
Volk iNview Case	VINVIEW-CASE
VISTAVIEW RETINAL CAMERA (Class I)	
Product Name	Product Code
VistaView	VVISTAVIEW
LENS ACCESSORIES (Class I)	
Product Name	Product Code
VitreoLens Handle Long	VVITHAN-LG
VitreoLens Handle for MQXL	VVITHAN-MQXL
Volk Infusion Handle	VINFHAN
Suture Ring	VSR2
NON-MEDICAL LENS ACCESSORIES (N/A)	
Product Name	Product Code
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
Volk Sterilization Case Small	VSCA
Volk Sterilization Case Large	VSCB
Volk Lens Pen	VLENSPEN
Precision Optical Lens Cleaner (1 box of 24)	VPOLC1
6 boxes Precision Optical Lens Cleaner	VPOLC6
12 boxes Precision Optical Lens Cleaner	VPOLC12
Case-Precision Optical Lens Cleaner (108 boxes of 24)	VPOLCCASE
Precision Optical Lens Cleaner-1000pcs	VPOLCBULK