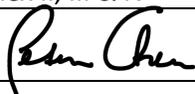




Declaration of Conformity

Manufacturer		European Union Authorized Representative
Volk Optical Inc. 7893 Enterprise Drive Mentor, Ohio 44060 USA Tel: +1 (800) 345-8655 Fax: +1 (440) 942-2257 volk@volk.com www.volk.com SRN: Not yet assigned by EUDAMED.		Rudolf Riester GmbH Bruckstraße 31 72417 Jungingen Germany Tel: (+49) 7477-9270-0 Fax: (+49) 7477-9270-70 info@riester.de www.riester.de SRN: Not yet assigned by EUDAMED.
Product	Lenses, iNview & VistaView, Merlin & ROLS Surgical Systems, and accessories (see Appendix A)	
Risk Classification	Class I devices, Rules 1, 10 & 13 according to Annex VIII of the MDR	
We hereby declare that this declaration of conformity is issued under the sole responsibility of Volk Optical Inc. and that the above-mentioned devices are in conformity with the EU Medical Devices Regulation (MDR), Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices.		
Conformity Assessment	Annex II, III & IV	
Signature		
Name	Peter Chen	
Position	Chief Financial and Operating Officer	
Date	May 26, 2021	
Place of Issue of Declaration	Mentor, Ohio	



Appendix A:

BINOCULAR INDIRECT OPHTHALMOSCOPE (BIO) LENSES				
Product Code	Product Name	Rule	Basic UDI-DI	Intended Purpose
V14LC	14D Large Clear	1	81160801BIOSE	The Volk Optical BIO Lenses are intended for visualization during diagnosis and laser therapy of the human retina (fundus) using a binocular indirect ophthalmoscope.
V15LC	15D Large Clear	1		
V20LC	20D Large Clear	1		
V20LC-BE	20D – Blue Ring	1		
V20LC-GD	20D – Gold Ring	1		
V20LC-GN	20D – Green Ring	1		
V20LC-PE	20D – Purple Ring	1		
V20LC-RD	20D – Red Ring	1		
V20LC-SR	20D – Silver Ring	1		
V20LC-CC	20D – Custom Color Ring	1		
K20LC	20LC (Distributor Version)	1		
L20LC	20LC (Distributor Version)	1		
VP20LC-PK	20LC (Distributor Version)	1		
V25LC	25D Large Clear	1		
V28LC	28D Large Clear	1		
V28LC-BE	28D – Blue Ring	1		
V28LC-GD	28D – Gold Ring	1		
V28LC-GN	28D – Green Ring	1		
V28LC-PE	28D – Purple Ring	1		
V28LC-RD	28D – Red Ring	1		
V28LC-SR	28D – Silver Ring	1		
L28LC	28LC (Distributor Version)	1		
V30LC	30D Large Clear	1		
V30SC	30D Small Clear	1		
V40LC	40D Large Clear	1		
VPRC	Pan Retinal 2.2 Clear	1		
VPRC-BE	Pan Retinal 2.2 – Blue Ring	1		
VPRC-GD	Pan Retinal 2.2 – Gold Ring	1		
VPRC-GN	Pan Retinal 2.2 – Green Ring	1		
VPRC-PE	Pan Retinal 2.2 – Purple Ring	1		
VPRC-RD	Pan Retinal 2.2 – Red Ring	1		
VPRC-SR	Pan Retinal 2.2 – Silver Ring	1		
LPRC	Pan Retinal 2.2 (Distributor Version)	1		
VMP5.5	Macula Plus 5.5	1		
VDGTLCF	Digital Clear Field	1		
VDGTLCF-BK	Digital Clear Field – Black Ring	1		
VDGTLCF-GD	Digital Clear Field – Gold Ring	1		
VDGTLCF-GN	Digital Clear Field – Green Ring	1		
VDGTLCF-PE	Digital Clear Field – Purple Ring	1		
VDGTLCF-RD	Digital Clear Field – Red Ring	1		
VDGTLCF-SR	Digital Clear Field – Silver Ring	1		
VDGTLCM	Digital Clear Mag	1		
VSLV20	Silver 20D	1		
VSLV28	Silver 28D	1		
C20	20D Cielo	1		
C28	28D Cielo	1		
V20LCACSPV	20D Clear ACS® PermaView	1		
V28LCACSPV	28D Clear ACS® PermaView	1		



NON-CONTACT SLIT LAMP LENSES				
Product Code	Product Name	Rule	Basic UDI-DI	Intended Purpose
V60C	60D Clear	1	81160801SLITNG	The Volk Optical Non-Contact Slit Lamp Lenses are intended for visualization during diagnosis and laser therapy of the human retina (fundus) using a slit lamp.
V78C	78D Clear	1		
V78C-BE	78D Clear – Blue Ring	1		
V78C-GD	78D Clear – Gold Ring	1		
V78C-GN	78D Clear – Green Ring	1		
V78C-PE	78D Clear – Purple Ring	1		
V78C-RD	78D Clear – Red Ring	1		
V78C-SR	78D Clear – Silver Ring	1		
V78C-CC	78D Clear – Custom Color Ring	1		
L78C	78D Clear (Distributor Version)	1		
K78C-BE	78D Clear (Distributor Version)	1		
VP78C-PK	78D Clear (Distributor Version)	1		
V90C	90D Clear	1		
V90C-BE	90D Clear – Blue Ring	1		
V90C-GD	90D Clear – Gold Ring	1		
V90C-GN	90D Clear – Green Ring	1		
V90C-PE	90D Clear – Purple Ring	1		
V90C-RD	90D Clear – Red Ring	1		
V90C-SR	90D Clear – Silver Ring	1		
V90C-CC	90D Clear – Custom Color Ring	1		
L90C	90D Clear (Distributor Version)	1		
K90C-BE	90D Clear (Distributor Version)	1		
VP90C-PK	90D Clear (Distributor Version)	1		
VSLV78	Silver 78D	1		
VSLV90	Silver 90D	1		
C78	78D Cielo	1		
C90	90D Cielo	1		
VS66	Super 66° Stereo Fundus	1		
VS66-BE	Super 66° – Blue Ring	1		
VS66-GD	Super 66° – Gold Ring	1		
VS66-GN	Super 66° – Green Ring	1		
VS66-PE	Super 66° – Purple Ring	1		
VS66-RD	Super 66° – Red Ring	1		
VS66-SR	Super 66° – Silver Ring	1		
VSFNC	Super Field° NC	1		
VSFNC-BE	Super Field° NC – Blue Ring	1		
VSFNC-GD	Super Field° NC – Gold Ring	1		
VSFNC-GN	Super Field° NC – Green Ring	1		
VSFNC-PE	Super Field° NC – Purple Ring	1		
VSFNC-RD	Super Field° NC – Red Ring	1		
VSFNC-SR	Super Field° NC – Silver Ring	1		
KSFNC-BE	Super Field° NC (Distributor Version)	1		
VPSFNC-PK	Super Field° NC (Distributor Version)	1		
VSPXL	Super Pupil° XL	1		
VSVF	Super Vitreo Fundus°	1		
VDGTL1	Digital 1.0X Imaging	1		
VDGTLWF	Digital Wide Field°	1		
VDGTLWF-BK	Digital Wide Field° – Black Ring	1		
VDGTLWF-GD	Digital Wide Field° – Gold Ring	1		
VDGTLWF-GN	Digital Wide Field° – Green Ring	1		
VDGTLWF-PE	Digital Wide Field° – Purple Ring	1		
VDGTLWF-RD	Digital Wide Field° – Red Ring	1		



VDGTLWF-SR	Digital Wide Field® – Silver Ring	1		
VDGTLWF-CC	Digital Wide Field® – Custom Color	1		
KDGLWF	Digital Wide Field® (Distributor Version)	1		
VPDGLWF-PK	Digital Wide Field® (Distributor Version)	1		
VDGLHM	Digital High Mag®	1		
VDGLHM-BK	Digital High Mag® – Black Ring	1		
VDGLHM-GD	Digital High Mag® – Gold Ring	1		
VDGLHM-GN	Digital High Mag® – Green Ring	1		
VDGLHM-PE	Digital High Mag® – Purple Ring	1		
VDGLHM-RD	Digital High Mag® – Red Ring	1		
VDGLHM-SR	Digital High Mag® – Silver Ring	1		
GONIOSCOPY LENSES				
Product Code	Product Name	Rule	Basic UDI-DI	Intended Purpose
V3MIR	3-Mirror Gonio Fundus NF	1	81160801GONIO GU	Volk Optical's Gonioscopy Lenses are indicated for use as diagnostic contact lenses for eye examinations (including the anterior chamber, trabecular meshwork, central retina, and peripheral retina) and use in the therapy of intraocular abnormalities.
V3MIRANF+	3-Mirror Gonio Fundus ANF+	1		
VU3MIR	3-Mirror Gonio Fundus (Uncoated) NF	1		
VU3MIRANF+	3-Mirror Gonio Fundus (Uncoated) ANF+	1		
VE3MIR	3 Mirror Lens (Distributor Version)	1		
VG1	G-1 Glass Trabeculum Glass Flange	1		
VG1NF	G-1 Glass Trabeculum No Flange No Fluid	1		
VG2	G-2 Glass Trabeculum Glass Flange	1		
VG2NF	G-2 Glass Trabeculum No Flange No Fluid	1		
VG3	G-3 Glass Gonio Fundus Glass Flange	1		
VG3NF	G-3 Glass Gonio Fundus No Flange No Fluid	1		
VG3MININF	G-3 Glass Gonio Fundus Mini No Flange No Fluid	1		
VEG3	G-3 Goniofundus (Distributor Version)	1		
VG4	G-4 Glass Gonio Glass Flange Fluid	1		
VG4LNF	G-4 Glass Hand Held Gonio (Large Ring) No Flange No Fluid	1		
VG4SNF	G-4 Glass Hand Held Gonio (Small Ring) No Flange No Fluid	1		
VG4HAN2	G-4 Glass 2 in 1 Handle Gonio No Flange No Fluid 3.5"	1		
VEG4	G-4 Goniolaser (Distributor Version)	1		
VG4HM	G-4 Glass High Mag Gonio Flange (Large Ring)	1		
VG4HMLNF	G-4 Glass High Mag Gonio No Flange (Large Ring) No Fluid	1		
VG4HMSNF	G-4 Glass High Mag Gonio No Flange (Small Ring) No Fluid	1		
VG4HMHAN2	G-4 Glass High Mag 2 in 1 Handle Gonio No Flange No Fluid	1		
VEG4HM	G-4 HighMag (Distributor Version)	1		
VG6LNF	G-6 Glass Hand Held Gonio – Large	1		
VG6HAN2	G-6 Glass NF 2 in 1 Handle	1		
V4MANF+	Mini 4 Mirror ANF+	1		
VSLT	Selective Laser Trabeculoplasty (SLT)	1		
VESLT	SLT Lens (Distributor Version)	1		
VMSLT	Rapid SLT	1		
VSGACS	Surgical Gonio	1		
VESGACS	Surgical Gonio (Distributor Version)	1		
VTSTVG	Alcon Vold TVG Surgical Gonio	1		
VTSVVG	Volk Vold Surgical Gonio	1		



CONTACT LASER & DIAGNOSTIC LENSES				
Product Code	Product Name	Rule	Basic UDI-DI	Intended Purpose
VAC	Area Centralis	1	81160801CONTA CTJR	Indicated for use as diagnostic contact lenses for eye fundus examinations and use in the therapy of intraocular abnormalities.
VACNF	Area Centralis NF	1		
VACANF+	Area Centralis ANF+	1		
VEAC	Area Centralis® (Distributor Version)	1		
VEPNF	Equator Plus® NF	1		
VEPANF+	Equator Plus® ANF+	1		
VHRC	HR Centralis	1		
VEHRC	HR Centralis (Distributor Version)	1		
VHRWF	High Resolution Wide Field	1		
VEHRWF	High Resolution Wide Field (Distributor Version)	1		
VPDT	PDT Lens	1		
VQPED	Quad Pediatric	1		
VQFL	QuadrAspheric®	1		
VQFLNF	QuadrAspheric® NF	1		
VQFLANF+	QuadrAspheric® ANF+	1		
VEQFL	QuadrAspheric® (Distributor Version)	1		
VSMAC2.2	Super Macula® 2.2	1		
VSQUAD160	Super Quad® 160	1		
VSQUAD160NF	Super Quad® 160 NF	1		
VESQUAD160	Super Quad® 160 (Distributor Version)	1		
VTE	Trans Equator®	1		
VTENF	Trans Equator® NF	1		
VTEANF+	Trans Equator® ANF+	1		
VETE	Trans Equator® (Distributor Version)	1		
VCAPS	Capsulotomy	1		
VECAPS	Capsulotomy Lens (Distributor Version)	1		
VCD	Centralis Direct®	1		
VCDANF+	Centralis Direct® ANF+	1		
VFUNDUS	Fundus	1		
VFUNDUS20	Fundus 20MM	1		
VIRID	Iridectomy	1		
VEIRID	Iridectomy (Distributor Version)	1		
VMPIRID	MagPlus Iridectomy	1		
VEMPIRID	MagPlus Iridectomy (Distributor Version)	1		
VBIRID	Blumenthal Iridotomy	1		
VEBIRID	Blumenthal Iridotomy (Distributor Version)	1		
VBSL	Blumenthal Suturelysis	1		
VIMV	Volk Idrees Mid-Vitreous	1		
VEIMV	Idrees MidVitreous (Distributor Version)	1		
VSMV	Volk Singh Mid-Vitreous	1		
VESMV	Singh MidVitreous (Distributor Version)	1		
VITRECTOMY LENSES				
Product Code	Product Name	Rule	Basic UDI-DI	Intended Purpose
VCRLVIT	Central Retinal	1	81160801VITVU	Volk Vitrectomy Contact Lenses are indicated for use as diagnostic contact lenses for eye fundus examinations and use in the therapy of intraocular abnormalities.
VCRLVITSSV	Central Retinal SSV®	1		
VDVVIT	DynaView 156	1		
VHRXVIT	HRX Vit	1		
VHRXVITSSV	HRX SSV® Vit	1		
VMQVIT	Mini Quad®	1		
VMQVITSSV	Mini Quad® SSV®	1		



VMQXLVIT	Mini Quad® XL	1		
VMQXLVITSSV	Mini Quad® XL SSV®	1		
VSMACVIT	Super Macula®	1		
VMQVITACS	Mini Quad® ACS®	1		
VMQVITSSVACS	Mini Quad® SSV® ACS®	1		
VCRLVITACS	Central Retinal ACS®	1		
VCRLVITSSVACS	Central Retinal SSV ACS®	1		
VHRXVITACS	HRX Vit ACS®	1		
VHRXVITSSVACS	HRX Vit SSV® ACS®	1		
VHRD1XACS	HR Direct 1x Vit	1		
VHRD1XNSRACS	HR Direct 1x NSR Vit	1		
VHRDBCACS	HR Direct Bi-concave	1		
VHRDHMACS	HR Direct HM Vit	1		
VHRDHMNSRACS	HR Direct HM NSR Vit	1		
VHRD20PACS	HR Direct 20° Prism Vit	1		
VPRISMSSVACS	15° Prism SSV® ACS®	1		
V30PRISMSSVACS	30° Prism SSV® ACS®	1		
V45PRISMSSVACS	45° Prism SSV® ACS®	1		
VAFXSSVACS	Air Fluid Exchange SSV® ACS®	1		
VFLATSSVACS	Flat SSV® ACS®	1		
VFHMSSVACS	Direct Image High Mag ACS®	1		
VMFSSVACS	Mid Field SSV® ACS®	1		
INVIEW RETINAL CAMERA				
Product Code	Product Name	Rule	Basic UDI-DI	Intended Purpose
VINVIEW-5S	Volk iNview for iPhone 5s	1	81160801INVUE	The Volk iNview ophthalmic camera is intended to take photographs of the retina of the eye for the purposes of general visualization and patient education.
VINVIEW-6	Volk iNview for iPhone 6	1		
VINVIEW-TCH	Volk iNview for iPod Touch	1		
VINVIEWC-TCH	Volk iNview Touch Camera	1		
VISTAVIEW RETINAL CAMERA				
Product Code	Product Name	Rule	Basic UDI-DI	Intended Purpose
VVISTAVIEW	VistaView	10	81160801VVB3	The Volk VistaView is a mydriatic fundus camera that is intended to capture and store images of the fundus of the dilated eye.
LENS ACCESSORIES				
Product Code	Product Name	Rule	Basic UDI-DI	Intended Purpose
VVITHAN-LG	VitreoLens Handle Long	1	81160801VITHNX	The Volk VitreoLens® Handle is an ophthalmic forceps device and is intended to aid in manual ophthalmic surgical procedures.
VVITHAN-MQXL	VitreoLens Handle for MQXL	1		
VINFHAN	Volk Infusion Handle	1	81160801VINFHK Y	The Volk Infusion Handle is an ocular surgery irrigation device intended to be suspended over the ocular area during ophthalmic surgery to deliver continuous, controlled irrigation to the surgical field.



VSR52	Suture Ring	1	81160801SRS2NA	The Volk Suture Ring is an ophthalmic ring device and is intended to aid in manual ophthalmic surgical procedures.
VCLEARPOD90D	Volk ClearPod, 90D	1	81160801CLPODE Z	The Volk ClearPod is intended to reduce lens fogging while performing eye examinations on patients wearing facemasks.
VCLEARPOD78D	Volk ClearPod, 78D	1		
VCLEARPODSFNC	Volk ClearPod, SFNC	1		
VCLEARPODDGTLWF	Volk ClearPod, DGTLWF	1		
MERLIN® ROTATIONAL ASSEMBLY (RA)				
Product Code	Product Name	Rule	Basic UDI-DI	Intended Purpose
11179	Rotational Assembly	1	81160801MRAU4	Provides attachment assembly for Lens Positioning Unit with 360° rotation about optical axis.
MERLIN® CONDENSER LENS ASSEMBLY (CLA) Auto				
Product Code	Product Name	Rule	Basic UDI-DI	Intended Purpose
11375	Assy, CLA, Auto, 175mm	13	81160801MCLAA UTONM	Provides attachment assembly for Lens Positioning Unit with 360° rotation about optical axis.
11376	Assy, CLA, Auto, 200mm	13		
11181	Auto CLA (No Condensing Lens)	13		
MERLIN® CONDENSER LENS ASSEMBLY (CLA) Manual				
Product Code	Product Name	Rule	Basic UDI-DI	Intended Purpose
11377	Assy, CLA, Manual, 175mm	1	81160801MCLAM ANFN	Provides attachment assembly for Lens Positioning Unit with 360° rotation about optical axis.
11378	Assy, CLA, Manual, 200mm	1		
11270	Manual CLA (No Condensing Lens)	1		
MERLIN® LENS POSITIONING UNIT (LPU)				
Product Code	Product Name	Rule	Basic UDI-DI	Intended Purpose
11171	Assy, LPU, For RA, 175mm	1	81160801MLPU MV	Holds the lens over the patient with full-scale adjustment.
11172	Assy, LPU, For RA, 200mm	1		
11173	Assy, LPU, For CLA, 175mm	1		
11174	Assy, LPU, For CLA, 200mm	1		
MERLIN® LENSES				
Product Code	Product Name	Rule	Basic UDI-DI	Intended Purpose
11182	Assy, Mid-Field NC Lens	1	81160801MLENS HK	The Merlin non-contact lens is the optical viewing element which attaches to the LPU for viewing the eye anatomy.
11183	Assy, Wide Angle NC Lens	1		
11184	Assy, Small Orbit Wide Angle NC Lens	1		
ROLS® ∞ Manual				
Product Code	Product Name	Rule	Basic UDI-DI	Intended Purpose
11313	ROLS Infinity, Zeiss – Manual	1	81160801ROLSIN FM5G	Provides high resolution reinverted images during vitreoretinal surgery
11315	ROLS Infinity, Leica – Manual	1		
ROLS® ∞ Auto				
Product Code	Product Name	Rule	Basic UDI-DI	Intended Purpose
11363	ROLS Infinity, Zeiss - Auto	13	81160801ROLSIN FA4Q	Provides high resolution reinverted images during vitreoretinal surgery
11364	ROLS Infinity, Leica - Auto	13		
MERLIN® MICROSCOPE MOUNTING ADAPTER KITS				
Product Code	Product Name	Rule	Basic UDI-DI	Intended Purpose
11411	Merlin RA Mount, Leica 690	1	81160801MMOU NTL2	
11552	Merlin RA Mount, Zeiss MD	1		



11481	Merlin CLA Mount, Leica 690	1		Serve as mounting hardware to attach Merlin devices to a microscope.
11553	Merlin CLA Mount, Zeiss MD	1		
11409	Merlin Mount, Leica	1		
11408	Merlin Mount, Zeiss	1		
11410	Merlin Mount, Moleller Weidel	1		
11412	Merlin Mount, Takagi	1		
11413	Merlin Mount, Topcon	1		
11654	Merlin Mount, Inami	1		
11732	Merlin Mount, Alcon	1		
11947	Merlin Mount, Topcon OMS90	1		
12171	Merlin Mount, Leica M822	1		
12159	Merlin Mount, Leica M690	1		
12160	Merlin Mount, L 820/840/841/844	1		
12161	Merlin Mount, MW HS HiR	1		
12163	Merlin Mount, Zeiss Visu	1		
11425	Merlin Mount, Spacer Kit	1		
MERLIN® POWER SYNC CABLES				
Product Code	Product Name	Rule	Basic UDI-DI	Intended Purpose
11627	Merlin Power Sync Cable - 18"	1	81160801MSYNC M8	Passes power between the Merlin CLA & ROLS Infinity.
11669	Merlin Power Sync Cable - 24"	1		
ROLS® REINVERTER				
Product Code	Product Name	Rule	Basic UDI-DI	Intended Purpose
VROLS-Z	ROLS Reinverter - Zeiss	1	81160801VROLSP C	The ROLS is an advanced panoramic viewing system that provides reinverted viewing during vitreoretinal surgery, delivering high resolution, correctly-oriented retinal images.
VROLS-Z+	ROLS Reinverter - Zeiss +	1		
VROLS-L	ROLS Reinverter - Leica	1		
VROLS-L+	ROLS Reinverter - Leica+	1		
VROLS-LX	ROLS Reinverter - Leica, Open Flange	1		
VROLS-LX+	ROLS Reinverter - Leica+, Open Flange	1		



Vertimas iš anglų kalbos į lietuvių

ATITIKTIES DEKLARACIJA

GAMINTOJAS	Volk Optical Inc. 7893 Enterprise kelias Mentor, Ohio 44060 JAV Tel: +1 (800) 345-8655
ATSTOVAS EUROPOJE	Rudolf Riester GmbH Bruckstraße 31 72417 Jungingen Vokietija Tel: (+49) 7477-9270-0
PRODUKTAS	Produkto tipas: Lęšiai Obje, „iNview“ ir „VistaView“, „Merlin & ROLS“ chirurginės sistemos ir priedai (žr. A priedą)
KLASIFIKACIJA	I klasės prietaisai, 1, 10 ir 13 taisyklės pagal MDR VIII priedą
Mes deklaruojame, kad ši atitikties deklaracija yra išduodama „Volk Optical Inc.“ atsakomybe ir kad pirmiau minėti prietaisai atitinka ES medicinos prietaisų reglamentą (MDR), Europos Parlamento reglamentą (ES) 2017/745 ir 2017 m. balandžio 5 d. Tarybos direktyvą dėl medicinos prietaisų.	
Atitikties įvertinimas	II, III ir IV priedai
PARAŠAS	/PARAŠAS/
VARDAS	Peter Chen
PAREIGOS	Finansų ir veiklos vadovas
DATA	2021 m. gegužės 26 d.
VIETA	Mentor, Ohio



Vertimas iš anglų kalbos į lietuvių

ATITIKTIES DEKLARACIJA

GAMINTOJAS	Volk Optical Inc. 7893 Enterprise kelias Mentor, Ohio 44060 JAV Tel: +1 (800) 345-8655
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Atitikties įvertinimas	II, III ir IV priedai
PARAŠAS	/PARAŠAS/
VARDAS	Peter Chen
PAREIGOS	Finansų ir veiklos vadovas
DATA	2021 m. gegužės 26 d.
VIETA	Mentor, Ohio