




A HALMA COMPANY

## DECLARATION OF CONFORMITY

<b>MANUFACTURER</b>	Volk Optical Inc. 7893 Enterprise Drive Mentor, Ohio 44060 USA Tel: 800-345-8655
<b>EUROPEAN REPRESENTATIVE</b>	Keeler Limited Clewer Hill Road Windsor SL4 4AA UK Tel: +44(0) 1753 857177
<b>PRODUCT</b>	Product Type:      Lens and lens accessories Sterile single use lenses Catalog Number:    As listed in attachment
<b>CLASSIFICATION</b>	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
<b>NOTIFIED BODY</b>	BSI (0086)
<p>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.</p>	
<b>STANDARDS APPLIED</b>	ISO 13485
<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 L. MASTORES
<b>POSITION</b>	PRESIDENT
<b>DATE</b>	JULY 12, 2016



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VOLK BINOCULAR INDIRECT LENSES	
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
VOLK CLASSIC SLIT LAMP LENSES	
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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### VOLK SUPER SERIES SLIT LAMP LENSES

Product Name	Product Code
Super 66 <sup>®</sup> Stereo Fundus	VS66
Super 66 <sup>®</sup> – Blue Ring	VS66-BE
Super 66 <sup>®</sup> – Green Ring	VS66-GN
Super 66 <sup>®</sup> – Purple Ring	VS66-PE
Super 66 <sup>®</sup> – Red Ring	VS66-RD
Super 66 <sup>®</sup> – Gold Ring	VS66-GD
Super 66 <sup>®</sup> – Silver Ring	VS66-SR
SuperField <sup>®</sup> NC	VSFNC
SuperField <sup>®</sup> NC – Blue Ring	VSFNC-BE
SuperField <sup>®</sup> NC – Green Ring	VSFNC-GN
SuperField <sup>®</sup> NC – Purple Ring	VSFNC-PE
SuperField <sup>®</sup> NC – Red Ring	VSFNC-RD
SuperField <sup>®</sup> NC – Gold Ring	VSFNC-GD
SuperField <sup>®</sup> NC – Silver Ring	VSFNC-SR
SuperPupil <sup>®</sup> XL	VSPXL
Super Vitreo Fundus <sup>®</sup>	VSVF
Super Vitreo Fundus <sup>®</sup> – Blue Ring	VSVF
Super Vitreo Fundus <sup>®</sup> – Green Ring	VSVF
Super Vitreo Fundus <sup>®</sup> – Purple Ring	VSVF
Super Vitreo Fundus <sup>®</sup> – Red Ring	VSVF
Super Vitreo Fundus <sup>®</sup> – Gold Ring	VSVF
Super Vitreo Fundus <sup>®</sup> – Silver Ring	VSVF
Digital 1.0X Imaging	VDGTL1
Digital Wide Field <sup>®</sup>	VDGTLWF
Digital Wide Field <sup>®</sup> – Black Ring	VDGTLWF-BK
Digital Wide Field <sup>®</sup> – Green Ring	VDGTLWF-GN
Digital Wide Field <sup>®</sup> – Purple Ring	VDGTLWF-PE
Digital Wide Field <sup>®</sup> – Red Ring	VDGTLWF-RD
Digital Wide Field <sup>®</sup> – Gold Ring	VDGTLWF-GD
Digital Wide Field <sup>®</sup> – Silver Ring	VDGTLWF-SR
Digital High Mag <sup>®</sup>	VDGTLHM
Digital High Mag <sup>®</sup> – Black Ring	VDGTLHM-BK
Digital High Mag <sup>®</sup> – Green Ring	VDGTLHM-GN
Digital High Mag <sup>®</sup> – Purple Ring	VDGTLHM-PE
Digital High Mag <sup>®</sup> – Red Ring	VDGTLHM-RD
Digital High Mag <sup>®</sup> – Gold Ring	VDGTLHM-GD
Digital High Mag <sup>®</sup> – Silver Ring	VDGTLHM-SR

### VOLK CONTACT LASER & DIAGNOSTIC LENSES

Product Name	Product Code
SuperMacula <sup>®</sup> 2.2	VSMAC2.2
Area Centralis	VAC
Area Centralis ANF+	VACANF+
Area Centralis NF	VACNF
TransEquator <sup>®</sup>	VTE
TransEquator <sup>®</sup> ANF+	VTEANF+
TransEquator <sup>®</sup> NF	VTENF
QuadrAspheric <sup>®</sup>	VQFL
QuadrAspheric <sup>®</sup> ANF+	VQFLANF+
QuadrAspheric <sup>®</sup> NF	VQFLNF
SuperQuad <sup>®</sup> 160	VSQUAD160
SuperQuad <sup>®</sup> 160 NF	VSQUAD160NF
High Resolution Wide Field	VHRWF
PDT Lens	VPDT
EquatorPlus <sup>®</sup> ANF+	VEPANF+
EquatorPlus <sup>®</sup> NF	VEPNF
QuadPediatric	VQPED
Centralis Direct <sup>®</sup>	VCD



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VOLK CONTACT LASER & DIAGNOSTIC LENSES	
Product Name	Product Code
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 Idress MidVitreous	VIMV
VITRECTOMY LENSES	
Product Name	Product Code
MiniQuad®	VMQVIT
MiniQuad® SSV	VMQVITSSV
MiniQuad® XL	VMQXLVIT
MiniQuad® XL SSV	VMQXLVITSSV
MiniQuad® ACS	VMQVITACS
MiniQuad® XL ACS	VCMQXLVITACS
MiniQuad® SSV ACS	VMQVITSSVACS
MiniQuad® XL SSV ACS	VMQVITSSVACS
Central Retinal	VCRLVIT
Central Retinal SSV	VCRLVITSSV
Central Retinal ACS	VCRLVITACS
Central Retinal SSV ACS	VCRLVITSSVACS
SuperMacula	VSMACVIT
DynaView 156	VDVVIT
Flat SSV ACS	VFLATSSVACS
Flat ACS	VFLATAACS
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	VMFACS
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 Lens	VHRDBACACS
HR Direct HM NSR Vit Lens	VHRDHMNSRACS
HR Direct HM Vit Lens	VHRDHMACS
HR Direct 1x Vit Lens	VHRD1XACS
HR Direct 20Prism Vit Lens	VHRD20PACS
HRX Vit Lens	VHRXVIT
HRX SSV Vit Lens	VHRXVITSSV
HRX Vit ACS Lens	VHRXVITACS
HRX Vit SSV ACS Lens	VHRXVITSSVACS
ASSY, Offset OSA Lens, WA60L	11046
ASSY, Offset OSA Lens, WA60R	11047



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GONIO LENSES	
Product Name	Product Code
3 Mirror Gonio Fundus Lens NF	V3MIR
3 Mirror Gonio Fundus Lens ANF+	V3MIRANF+
3 Mirror Gonio Fundus Lens (Uncoated) NF	VU3MIR
3 Mirror Gonio Fundus Lens (Uncoated) ANF+	VU3MIRANF+
G-1 Glass Trabeculum Lens Glass Flange	VG1
G-1 Glass Trabeculum Lens No Flange No Fluid	VG1NF
G-2 Glass Trabeculum Lens Glass Flange	VG2
G-2 Glass Trabeculum Lens No Flange No Fluid	VG2NF
G-3 Glass Gonio Fundus Glass Flange	VG3
G-3 Glass Gonio Fundus Lens No Flange No Fluid	VG3NF
G-3 Glass Gonio Fundus Lens Mini No Flange No Fluid	VG3MININF
G-4 Glass Gonio Lens 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 Lens – Large	VG6LNF
G-6 Glass NF 2 in 1 Handle Lens	VG6HAN2
Mini 4 Mirror ANF+	V4MANF+
Selective Laser Trabeculoplasty (SLT)	VSLT
Surgical Gonio Lens	VSGACS
Transcend TVG Surgical Gonio	VTSTVG
VOLK SINGLE USE VITRECTOMY LENSES	
Product Name	Product Code
Disposable Direct Image Flat SSV®	VFLATSSVD
Disposable Direct Image Flat Vitrectomy Lens	VFD
Disposable Direct Image Wide Field Vitrectomy Lens	VWFD
Disposable Direct Image 1.5x Magnifying Vitrectomy Lens	VMD
Disposable Direct Image 30° Prism Vitrectomy Lens	V30PD
Disposable Direct Image Biconcave Vitrectomy Lens	VBCD
VOLK SINGLE USE CONTACT & LASER DIAGNOSTIC LENSES	
Product Name	Product Code
Capsulotomy Disposable	VCAPSD
Iridotomy Disposable	VIRIDD
VOLK SINGLE USE BINOCULAR INDIRECT LENSES	
Product Name	Product Code
Single Use 20D	V20LCD
Single Use 28D	V28LCD
VOLK SINGLE USE GONIO LENSES	
Product Name	Product Code
Single Use 4-Mirror Gonio	V4MIRD
Single Use 3-Mirror Gonio	V3MIRD
VOLK POWER ADAPTERS	
Product Code	Product Name
20D – 16D Transformer Adapter Lens	VAD20L-16
20D – 24D Transformer Adapter Lens	VAD20L-24
20D – 28D Transformer Adapter Lens	VAD20L-28
SuperField NC Minus Power Non-Contact Adapter	VSFMINUS
SuperField NC Plus Power Non-Contact Adapter	VSFPLUS



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<b>VOLK LID LENS ADAPTERS</b>	
<b>Product Name</b>	<b>Product Code</b>
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 VitreoFundus Lid Lens Adapter	VLLASVF
<b>VOLK CONTACT ADAPTERS</b>	
<b>Product Name</b>	<b>Product Code</b>
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+
<b>VOLK LENS ACCESSORIES</b>	
<b>Product Name</b>	<b>Product Code</b>
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
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	VSMSFNC
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	VLF
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