



Declaration of conformity

Medical Device Regulation (2017/745) of April 5th, 2017

We, Hoya Holdings N.V., hereby declare under our sole responsibility as manufacturer that the following class I medical devices:

- Hoya Single Vision Corrective Ophthalmic Lenses

Hilux (HL) (Trueform)	Hilux Kids	Nulux (NL) (Trueform)	Nulux EP/LX
Hilux Drivewear	Hilux Star	Nulux Active (A/B) (Trueform)	UV
Hilux High Curve	Spheric(al)	Nulux Sportive	LHI
Hilux Seamless Aspheric	Aspheric(al)	Nulux iDentity V+ (EyeGenius)	LHI-2
Hilux Lenticular (CX/CC)	Double Aspheric	Addpower (Trueform)	THI/THI-2
Hilux Thin	Stellify (SV/AS)	Lecture (A & B (Trueform))	SBX/SGX
EnRoute SV	EnRoute SV Pro	Cataract (SAS)	SBX-2/SGX-2
Sync III	Sync IIIi	Miyosmart	

- Hoya Bifocal Corrective Ophthalmic Lenses

C28 (CT28) (Trueform)	C25 (CT25)	S728 (Tri ST28)	S35
S28 (F28) (Trueform)	T28 (R28)	S25	Executive

- Hoya Progressive Corrective Ophthalmic Lenses

Lifestyle 3 Indoor/Urban/Outdoor	Lifestyle 3i Indoor/Urban/Outdoor	
Lifestyle 3 Close/Allround/Active	Lifestyle 3i Close/Allround/Active	
Hoyalux iD MySelf	Hoyalux Daynamic (11/14)	Hoyalux Sportive
Hoyalux iD (InStyle) (11/14)	Hoyalux iD LifeStyle V+ Clarity/Harmony (11/14)	
Hoyalux iD LifeStyle (11/14)	Hoyalux iD LifeStyle V+ X-Act Clarity/Harmony (11/14)	
Hoyalux iD MyStyle V+	Hoyalux iD MyStyle Open/Balance/Clear (11/14/16)	
Hoyalux iD Workstyle	Hoyalux iD MyStyle V+ EyeGenius	
Hoyalux Summit Pro (Trueform)	Hoyalux iD WorkStyle V+ Close/Screen/Space	
Hoyalux Summit CD (Trueform)	Hoyalux iD LifeStyle V+ X-Act Clarity/Harmony EyeGenius	
Hoyalux Summit Premium (11/15)	Hoyalux Summit Premium Individual (11/12/13/14/15/16/17)	
Hoyalux Balansis/Balansis i	Hoyalux Summit (13/15)	Hoyalux Tact (Trueform)
Hoyalux GP	Hoyalux (GP) Wide	Hoyalux GP High Curve
Hoyalux Amplitude (11/13/15) (TF)	Hoyalux Amplitude Mini (TF)	Hoyalux Amplitude Plus
EnRoute PAL	EnRoute PAL Pro	Argos (Short)

conform to the EU Regulation 2017/745 of April 5th, 2017, concerning medical devices. In particular to general safety and performance requirements (Annex I). And also comply to the following standards:

- ISO 8980-1/2/3/4/5;
- ISO 14889.

All supporting documentation is retained under the premises of the manufacturer.


Yasuro Mori
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Hoya Vision Care
Hoya Holdings N.V.
Radarweg 29
1043 NX Amsterdam
The Netherlands
Basic UDI-DI: See other side

Place: Amsterdam
Date: 26th of April 2021 (re-issue 4/22)
SRN: NL-MF-000.004.415

Organic Ophthalmic Lens:	Basic UDI-DI
Clear Ophthalmic Single Vision Lens 1.50	87202995187OLENS150SVCLXX
Clear Ophthalmic Bifocal Lens 1.50	87202995187OLENS150BFCLRX
Clear Ophthalmic Progressive Lens 1.50	87202995187OLENS150PRCLWN
Clear Ophthalmic Single Vision Lens 1.53	87202995187OLENS153SVCLYY
Clear Ophthalmic Bifocal Lens 1.53	87202995187OLENS153BFCLSR
Clear Ophthalmic Progressive Lens 1.53	87202995187OLENS153PRCLXP
Clear Ophthalmic Single Vision Lens 1.55	87202995187OLENS155SVCLZN
Clear Ophthalmic Progressive Lens 1.55	87202995187OLENS155PRCLYD
Clear Ophthalmic Single Vision Lens 1.56	87202995187OLENS156SVCL24
Clear Ophthalmic Progressive Lens 1.56	87202995187OLENS156PRCLYQ
Clear Ophthalmic Single Vision Lens 1.59	87202995187OLENS157SVCL2F
Clear Ophthalmic Progressive Lens 1.60	87202995187OLENS157PRCLZ3
Clear Ophthalmic Single Vision Lens 1.59	87202995187OLENS159SVCL35
Clear Ophthalmic Bifocal Lens 1.59	87202995187OLENS159BFCLUT
Clear Ophthalmic Progressive Lens 1.59	87202995187OLENS159PRCLZR
Clear Ophthalmic Single Vision Lens 1.60	87202995187OLENS160SVCLYC
Clear Ophthalmic Bifocal Lens 1.60	87202995187OLENS160BFCLS5
Clear Ophthalmic Progressive Lens 1.60	87202995187OLENS160PRCLX3
Clear Ophthalmic Single Vision Lens 1.67	87202995187OLENS167SVCL2U
Clear Ophthalmic Bifocal Lens 1.67	87202995187OLENS167BFCLUJ
Clear Ophthalmic Progressive Lens 1.67	87202995187OLENS167PRCLZG
Clear Ophthalmic Single Vision Lens 1.70	87202995187OLENS170SVCLYR
Clear Ophthalmic Progressive Lens 1.70	87202995187OLENS170PRCLXG
Clear Ophthalmic Single Vision Lens 1.74	87202995187OLENS174SVCL28
Clear Ophthalmic Progressive Lens 1.74	87202995187OLENS174PRCLYU
Photochromic Ophthalmic Single Vision Lens 1.50	87202995187OLENS150SVPHYW
Photochromic Ophthalmic Bifocal Lens 1.50	87202995187OLENS150BFPHSP
Photochromic Ophthalmic Progressive Lens 1.50	87202995187OLENS150PRPHXM
Photochromic Ophthalmic Single Vision Lens 1.53	87202995187OLENS153SVPH22
Photochromic Ophthalmic Bifocal Lens 1.53	87202995187OLENS153BFPH2Q
Photochromic Ophthalmic Progressive Lens 1.53	87202995187OLENS153PRPHYN
Photochromic Ophthalmic Single Vision Lens 1.55	87202995187OLENS155SVPH2Q
Photochromic Ophthalmic Progressive Lens 1.55	87202995187OLENS155PRPHZC
Photochromic Ophthalmic Single Vision Lens 1.56	87202995187OLENS156SVPH33
Photochromic Ophthalmic Progressive Lens 1.56	87202995187OLENS156PRPHZP
Photochromic Ophthalmic Single Vision Lens 1.59	87202995187OLENS159SVPH44
Photochromic Ophthalmic Progressive Lens 1.59	87202995187OLENS159PRPH2T
Photochromic Ophthalmic Single Vision Lens 1.60	87202995187OLENS160SVPHZB
Photochromic Ophthalmic Bifocal Lens 1.60	87202995187OLENS160BFPH24
Photochromic Ophthalmic Progressive Lens 1.60	87202995187OLENS160PRPHY2
Photochromic Ophthalmic Single Vision Lens 1.67	87202995187OLENS167SVPH3T
Photochromic Ophthalmic Progressive Lens 1.67	87202995187OLENS167PRPH2J
Polarized Ophthalmic Single Vision Lens 1.70	87202995187OLENS170SVPO29
Polarized Ophthalmic Progressive Lens 1.70	87202995187OLENS170PRPOYV
Polarized Ophthalmic Single Vision Lens 1.50	87202995187OLENS150SVPOZC
Polarized Ophthalmic Progressive Lens 1.50	87202995187OLENS150PRPOY3
Polarized Ophthalmic Single Vision Lens 1.53	87202995187OLENS153SVPO2G
Polarized Ophthalmic Progressive Lens 1.53	87202995187OLENS153PRPOZ4
Polarized Ophthalmic Single Vision Lens 1.55	87202995187OLENS155SVPO36
Polarized Ophthalmic Progressive Lens 1.55	87202995187OLENS155PRPOZS
Polarized Ophthalmic Single Vision Lens 1.59	87202995187OLENS159SVPO4J
Polarized Ophthalmic Progressive Lens 1.59	87202995187OLENS159PRPO39
Polarized Ophthalmic Single Vision Lens 1.60	87202995187OLENS160SVPOZR
Polarized Ophthalmic Bifocal Lens 1.60	87202995187OLENS160BFPOTJ
Polarized Ophthalmic Progressive Lens 1.60	87202995187OLENS160PRPOYG
Polarized Ophthalmic Single Vision Lens 1.67	87202995187OLENS167SVPO49
Polarized Ophthalmic Progressive Lens 1.67	87202995187OLENS167PRPO2Y

Mineral Ophthalmic Lens:	Basic UDI-DI
Clear Ophthalmic Single Vision Lens 1.52	87202995187MLENS152SVCLWB
Clear Ophthalmic Bifocal Lens 1.52	87202995187MLENS152BFCLQ4
Clear Ophthalmic Progressive Lens 1.52	87202995187MLENS152PRCLV2
Clear Ophthalmic Single Vision Lens 1.60	87202995187MLENS160SVCLW2
Clear Ophthalmic Bifocal Lens 1.60	87202995187MLENS160BFCLPT
Clear Ophthalmic Progressive Lens 1.60	87202995187MLENS160PRCLUR
Clear Ophthalmic Single Vision Lens 1.70	87202995187MLENS170SVCLWF
Clear Ophthalmic Progressive Lens 1.70	87202995187MLENS170PRCLV6
Clear Ophthalmic Single Vision Lens 1.80	87202995187MLENS180SVCLWU
Clear Ophthalmic Progressive Lens 1.80	87202995187MLENS180PRCLVK
Clear Ophthalmic Single Vision Lens 1.90	87202995187MLENS190SVCLX9
Photochromic Ophthalmic Single Vision Lens 1.52	87202995187MLENS152SVPHXA
Photochromic Ophthalmic Bifocal Lens 1.52	87202995187MLENS152BFPHR3
Photochromic Ophthalmic Progressive Lens 1.52	87202995187MLENS152PRPHVZ
Photochromic Ophthalmic Single Vision Lens 1.60	87202995187MLENS160SVPHWZ
Photochromic Ophthalmic Bifocal Lens 1.60	87202995187MLENS160BFPHQS
Photochromic Ophthalmic Progressive Lens 1.60	87202995187MLENS160PRPHVQ