



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 Lenticular (CX/CC)	Aspheric(al)	Nulux iDentity V+ (EyeGenius)	LHI-2
Hilux Thin	Double Aspheric	Addpower (Trueform)	THI/THI-2
Miyosmart	Stellify (SV/AS)	Lecture (A & B (Trueform))	SBX/SGX
EnRoute SV	EnRoute SV Pro		SBX-2/SGX-2
Sync III	Sync IIIi		

- Hoya Bifocal Corrective Ophthalmic Lenses

C28 (CT28) (Trueform)	C25 (CT25)	S728 (Tri ST28/Trifocal)	S35/FT35/D35
S28 (FT28) (Trueform)	T28 (RT28/R28)	S25	Executive

- Hoya Progressive Corrective Ophthalmic Lenses

Hoyalux iD Lifestyle 3 (i) Indoor/Urban/Outdoor	Hoyalux iD Lifestyle 3 (i) Close/Allround/Active	
Hoyalux iD Lifestyle 4 (i) Indoor/Urban/Outdoor	Hoyalux iD Lifestyle 4 (i) Close/Allround/Active	
Hoyalux iD MySelf	Supereader A/B	
Hoyalux iD Workstyle 3 Close/Screen/Space	Hoyalux Workstyle Business	
Hoyalux Worksmart Room	Hoyalux iD WorkStyle V+ Close/Screen/Space	
Hoyalux Daynamic (11/14)	Hoyalux iD LifeStyle V+ Clarity/Harmony (11/14)	
Hoyalux Sportive	Hoyalux iD LifeStyle V+ X-Act Clarity/Harmony (11/14)	
Hoyalux iD MyStyle V+	Hoyalux iD MyStyle Open/Balance/Clear (11/14/16)	
Hoyalux Summit Pro (Trueform)	Hoyalux iD MyStyle V+ EyeGenius	
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	EnRoute PAL	EnRoute PAL Pro
Hoyalux Amplitude (Mini)(11/13/15) (TF)	Hoyalux Amplitude Plus	Hoyalux Tact (Trueform)

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.


Ian Wells
CFO
Hoya Vision Care
Hoya Holdings N.V.
Radarweg 29
1043 NX Amsterdam
The Netherlands
Basic UDI-DI: See page 2

Place: Amsterdam
Date: 7th of November 2022 (re-issue 11/23)
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	87202995187OLENS150BFCLRQ
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 1.59	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 Progressive Lens 1.67	87202995187OLENS167PRCLZG
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 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 1.59	87202995187OLENS159SVPH44
Photochromic Ophthalmic Progressive Lens 1.59	87202995187OLENS159PRPH2T
Photochromic Ophthalmic Single Vision Lens 1.60	87202995187OLENS160SVPHZB
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 1.50	87202995187OLENS150SVPOZC
Polarized Ophthalmic Progressive Lens 1.50	87202995187OLENS150PRPOY3
Polarized Ophthalmic Single Vision Lens 1.53	87202995187OLENS153SVPOZG
Polarized Ophthalmic Progressive Lens 1.53	87202995187OLENS153PRPOZ4
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 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 1.81	87202995187MLENS181SVCLX7
Clear Ophthalmic Progressive Lens 1.81	87202995187MLENS181PRCLVW
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