

## Declaration of conformity

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

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

- Single Vision corrective ophthalmic lenses  
Maxxee SP Maxxee AS
- BiFocal corrective ophthalmic lenses  
Maxxee R28 Maxxee FT-28
- Progressive corrective ophthalmic lenses  
Maxxee Multifocal Maxxee Multifocal FreeForm  
Maxxee Multifocal Short Maxxee Multifocal FreeForm Short  
Maxxee Multifocal Plus FreeForm Maxxee Multifocal Plus FreeForm Short  
Maxxee Office A/B

conform to the general safety and performance requirements (Annex I) of the EU Regulation 2017/745 of April 5<sup>th</sup>, 2017, concerning medical devices and 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.



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

Place: Amsterdam  
Date: 26<sup>th</sup> of May 2023 (re-issue 5/24)  
SRN: NL-MF-000.004.415

<b>Organic Ophthalmic Lens:</b>	<b>Basic UDI-DI</b>
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 1.55	87202995187OLENS155SVCLZN
Clear Ophthalmic Progressive Lens 1.55	87202995187OLENS155PRCLYD
Clear Ophthalmic Single Vision Lens 1.59	87202995187OLENS159SVCL35
Clear Ophthalmic Single Vision Lens 1.60	87202995187OLENS160SVCLYC
Clear Ophthalmic Progressive Lens 1.60	87202995187OLENS160PRCLX3
Clear Ophthalmic Single Vision Lens 1.67	87202995187OLENS167SVCL2U
Clear Ophthalmic Progressive Lens 1.67	87202995187OLENS167PRCLZG
Photochromic Ophthalmic Single Vision Lens 1.50	87202995187OLENS150SVPHYW
Photochromic Ophthalmic Progressive Lens 1.50	87202995187OLENS150PRPHXM
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 1.60	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 Progressive Lens 1.60	87202995187OLENS160PRPOYG

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