



Form-No: HHQF-01 (Rev.1)

Document Type	Hoya Holdings BV <HHBV Quality Document>	Control No.	HHDOC-RA-13	Pages No.	1 / 3
		Effective date	01/05/2026	Revision No.	00
Subject	Declaration of Conformity – PPE Products				

We, HOYA Holdings B.V. (dba HOYA Vision Care), hereby declare under our sole responsibility as Legal manufacturer, that the below mentioned products are in conformity with the requirements of Regulation (EU) 2016/425 as Personal Protective Equipment (Category II) and the product standard EN ISO 16321-1. We have considered all basic requirements, as found in Annex II of this Regulation, as determined applicable to the devices mentioned below and assures conformity to the below List of Applicable standards.

All mounted ophthalmic lenses fulfill the requirements as per Rule 1, Annex VIII of the EU Regulation 2017/745 of April 05th, 2017 of the European Parliament and of the Council concerning medical devices including all subsequent amendments. Furthermore, our products conform to the General Safety and Performance Requirements listed in Annex I of the Regulation as well as the below List of Applicable standards.

Prescription eye protector for low impact resistance, Optical Class 1:

MODELS

Beta	Classic 10	Classic 11	Classic 12
Classic 56	Cruiser	Eagle	Echo
Foxtrot	Misfire	Quantum	Rebel
Sidewinder	SVNY	SVSS11	SVSS12
SVSS14	SVSS3	SV20FS	Urban 6
ZT35	ZT100	ZT200	ZT400
ZT500	ZT500G		

Mounted with prescription oculars that withstand High-Speed Particles (C) of Single Vision, Bifocal and Progressive design:

- HiLux 1.50 clear lenses, UV protection and photochromic;
- PNX 1.53 clear lenses and photochromic;
- PC 1.59 clear lenses and photochromic;

The EU type examination was carried out by:

ECS GmbH – European Certification Service

Obere Bahnstraße 74

73431 Aalen

Germany

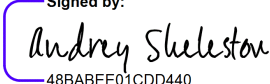
Notified body No: NB1883



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Type examination certificate number: C4566.2H; C4567.2H; C4568.2H (Oculars)
C4335.2H; C4336.2H; C4337.2H; C4338.2H; C4339.2H; C4340.2H; C4341.2H; C4342.2H;
C4343.2H; C4344.2H; C4345.2H; C4346.2H; C4498.2H; C4499.2H; C4500.2H; C4501.2H;
C4502.2H; C4503.2H; C4504.2H; C4505.2H; C4506.2H; C4507.2H; C4508.2H; C4509.2H;
C4510.2H; C4511.2H (Frames)

Legal Manufacturer:
HOYA Holdings B.V.
Radarweg 29
1043 NX Amsterdam
The Netherlands
SRN: NL-MF-000004415

Signed by:

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Andrey Shelestov
Management Representative
HOYA Holdings B.V.

Issue Date: 01st May 2026

Revision history

Rev No	Effective date	Approver	Author	Revised items	Outline and, Reason	Affected documents
00	01.05.2026	A. Shelestov	A. de. Roos	—	Initial Version	—



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List of Applicable Standards

Method of Conformity	Method of Conformity Title
ISO 16321-1:2021	Eye and face protection for occupational use, Part 1: General requirements
ISO 18526-1:2020	Eye and face protection - Test methods - Part 1: Geometrical optical properties
ISO 18526-2:2020	Eye and face protection - Test methods - Part 2: Physical optical properties
ISO 18526-3:2020	Eye and face protection - Test methods - Part 3: Physical and mechanical properties
ISO 18526-4:2020	Eye and face protection - Test methods - Part 4: Headforms
ISO 8980-1:2017	Part 1: Specifications for single-vision and multifocal lenses
ISO 8980-2:2017	Part 2: Specifications for power-variation lenses
ISO 8980-3:2022	Part 3: Transmittance specifications and test
ISO 8980-4:2006	Part 4: Specifications and test methods for anti-reflective coatings
ISO 8980-5:2005	Part 5: Minimum requirements for spectacle lens surfaces claimed to be abrasion-resistant
EN ISO 13485:2016/AC:2018	Medical device – Quality management system – Requirements for regulatory purposes