

SIA "Gravitis Enterprise Limited"

Technical File for Personal Protective Equipment

Regulation (EU) 2016/425

Annex A: Essential Health and Safety Requirements (EHSR) & Risk Assessment Checklist

Product: EclipsePro Series Solar Eclipse Glasses

(Models: EclipsePro Paper Series, EclipsePro Plastic Series)

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1.0	07/10/2025	Initial release: Extracted from main technical file and formatted as standalone document for improved clarity and Notified Body review

Document Approvals

This document has been reviewed and approved in accordance with the company's quality management procedures.

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EHSR Ref. (Annex II)	EHSR Requirement Title	Applicability & Justification	Identified Risks / Hazards	Control Measures Implemented	Verification / Evidence (Reference in Technical File)
1. GENERAL REQUIREMENTS APPLICABLE TO ALL PPE					
1.1 Design principles					
1.1.1	Ergonomics	Yes. PPE must allow the user to perform the risk-related activity (viewing the sun) normally while being protected.	Poor fit leading to discomfort, distraction, or the user removing the PPE prematurely.	Lightweight materials; frame design based on standard anthropometric data to fit a wide range of users; smooth, rounded edges.	Technical Drawings (SEG-TDP-001, SEGP-TDP-001); Final Assembly QC (Section 7.2)
1.1.2 Levels and classes of protection					
1.1.2.1	Optimum level of protection	Yes. The PPE must offer the highest level of protection without preventing its use.	If protection were higher (darker), the sun would be too dim to view effectively. If lower, it would be unsafe.	The filter's optical density is specified by EN ISO 12312-2:2015 to balance maximum safety with effective use for solar observation.	ICS Test Reports T18671-01-5 & T18671-01-7
1.1.2.2	Classes of protection appropriate to different levels of risk	Classes of protection appropriate to requiring a single, high class of protection. No other classes are appropriate or defined in the standard.	No. For direct solar observation, there is only one level of risk	N/A	N/A
1.2 Innocuousness of PPE					
1.2.1	Absence of inherent risks and other nuisance factors	Yes. The PPE must not create new risks.	Risk of chemical irritation, allergic reaction, or injury from the materials themselves.	All constituent materials are selected for innocuousness and verified against EU chemical regulations.	PP Frame: SGS RoHS Report ETR25206074 Paper Frame: Sinolight Report 2025020014 (Self-extinguishing property) Solar Filter: ICS Reports T18671-01-5 & T18671-01-7 Printing Inks (CMYK): SGS

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1.2.1.1	Suitable constituent materials	Yes. Materials and their decomposition products must be safe.	Potential for material degradation (certified inks/foils) are used, to release harmful substances.	Stable materials (PP, paperboard, Adhesive: SGS Report TSNEC2201663801	Hot Stamping Foil: SGS RoHS Report CANEC2108790201
				PP Additive (Glow Powder): DGRTTS MSDS RT20250430004 & SGS RoHS Report CANEC25006940001	All constituent materials are selected for innocuousness. Compliance with EU chemical regulations (e.g., RoHS, REACH SVHC) is verified not by relying on supplier-provided Safety Data Sheets, but through direct, empirical testing conducted by internationally accredited laboratories (SGS, ICS, Sinolight, DGRTTS). This provides the highest level of assurance.
				PP Frame: SGS Report ETR25206074	Inks: SGS Reports SHAEC24022975101 series
				Adhesive: SGS Report TSNEC2201663801	PP Additive: - DGRTTS Material Safety Data

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1.2.1.2	Satisfactory surface condition	Yes. Parts in contact with the user must be free of sharp edges, etc.	Scratches, cuts, or irritation from rough surfaces or sharp edges from the die-cutting or molding process.	Design specifies smooth, rounded edges. Manufacturing includes deburring (for plastic) and QC inspection for sharpness.	Sheet, Report No. RT20250430004 - SGS RoHS Test Report, Report No. CANEC25006940001
1.2.1.3	Maximum permissible user impedance	Yes. The PPE must minimize any impedance.	Restriction of field of vision.	The frame is designed to provide a wide field of vision through the filters while ensuring full coverage of the eyes.	Technical Drawings; Final Assembly QC (Section 7.2) Technical Drawings (SEG-TDP-001, SEGP-TDP-001)
1.3 Comfort and effectiveness					
1.3.1	Adaptation of PPE to user morphology	Yes. The PPE must fit a wide range of users correctly.	Poor fit leading to gaps and light leakage; glasses slipping off.	Flexible paperboard frame design and standard sizing of the plastic frame to accommodate various head sizes.	Technical Drawings (SEG-TDP-001, SEGP-TDP-001)
1.3.2	Lightness and strength	Yes. PPE must be as light as possible without compromising its strength.	Structural failure during normal handling (e.g., temples breaking off), leading to a loss of protection.	Use of lightweight materials. The design ensures structural integrity for normal handling forces.	ICS Test Reports T18671-01-5 & T18671-01-7 (clause 4.3); Final Assembly QC (Section 7.2)
1.3.3	Compatibility of different types of PPE	No. The IFU explicitly warns against using the product with other optical devices (binoculars, telescopes). The product is not intended for simultaneous use with other PPE.	N/A	N/A	Instructions for Use (SEG-IFU-001, SEGP-IFU)

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1.3.4	Protective clothing containing removable protectors Manufacturer's instructions and information	No. This product is not protective clothing. Yes. This is a critical requirement.	N/A User is not informed of risks, instructions for use, lifespan, markings, etc., leading to misuse and severe eye injury.	N/A A comprehensive, multi-language printed IFU is provided with each unit covering all points (a) through (I) as required. The DoC is accessible via a web address on the IFU.	N/A Master IFU Documents (SEG-IFU-001, SEGP-IFU-001); Marking Specification (SEG-MRK-001); Technical File Section 4.
1.4					

2. ADDITIONAL REQUIREMENTS COMMON TO SEVERAL TYPES OF PPE

2.1 - 2.3	PPE with adjustment systems; enclosing parts of body; for face, eyes, respiratory system	Applicable only for 2.3 , as the product is eye protection without adjustment systems (2.1) and is an open-frame design not liable to trap perspiration (2.2).	2.3(a): Restriction of field of vision: Frame obstructs peripheral view.	2.3(a): The frame is designed to provide a wide, unobstructed viewing area through the filters, minimizing peripheral obstruction while ensuring full eye coverage. The extreme darkness of the filter is a required protective characteristic (see 3.9.1), not a defect under 2.3(a).	Technical Drawings (SEG-TDP-001, SEGP-TDP-001)
			2.3(b): Optical Quality: Poor optical quality (distortion) could hinder effective viewing.	2.3(b): High-quality polymer solar filter is used, tested for optical neutrality and quality.	ICS Test Reports T18671-01-5 & T18671-01-7 (confirming optical quality per EN ISO 12312-2)
			2.3(c): Misting: Not a significant risk due to open-frame design.	2.3(c): N/A (Risk is negligible).	
2.4	PPE subject to ageing	Yes. The solar filter's protective properties can degrade over time.	Degradation of the filter due to UV exposure, humidity, or physical damage, leading to a reduction in protection.	A maximum service life of 3 years from the date of manufacture is established as the primary control for aging-related risks.	Instructions for Use (SEG-IFU-001); Technical File Section 4.

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2.12	PPE bearing one or more identification markings	Yes. Markings are required for safety and traceability.	User cannot identify the product or its production origin. Inability to isolate a group of products in case of a quality issue.	See Appendix 1: Rationale for Product Service Life This control is supplemented by the mandatory instruction in the IFU for users to visually inspect the product for any damage before each use. Hierarchical Traceability System: Each unit is marked with a unique serial number and QR code, fulfilling the requirement for an element allowing identification. This serial number links to the corresponding manufacturing batch record in our database. This system allows for precise unit-level verification and enables the grouping of products by production run, facilitating effective quality control.	Marking Specification (SEG-MRK-001, SEGP-MRK-001); Master IFU Documents; Technical File Section 4.
2.5 - 2.11, 2.13, 2.14	(Other requirements)	No. These requirements relate to PPE for different risks (e.g., getting caught in machinery, explosive atmospheres, high-visibility, multiple risks beyond radiation) and are not applicable.	N/A	N/A	N/A

3. ADDITIONAL REQUIREMENTS SPECIFIC TO PARTICULAR RISKS

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3.1 - 3.5	Protection against mechanical impact, falls, vibration, compression, drowning, noise	No. This PPE is not designed to protect against any of these risks. The intended use is for radiation protection during a stationary observation activity.	N/A	N/A	N/A
3.6 Protection against heat and/or fire					
3.6.1	PPE constituent materials	No. The PPE is intended solely for solar observation and is not designed for use in high-temperature or fire-risk environments. Heat and flame protection requirements do not apply.	N/A	N/A	N/A
3.6.2	Complete PPE ready for use	No. This section pertains to high-temperature environments and hot splashes, which are not foreseeable conditions of use for solar eclipse glasses.	N/A	N/A	N/A
3.7 & 3.8	Protection against cold; Protection against electric shock	No. The product is not intended for use in extreme cold environments or for protection against electrical shock.	N/A	N/A	N/A
3.9 Radiation protection					
3.9.1	Non-ionising radiation	Yes. This is the product's primary and sole protective function.	Primary Hazard: Exposure of the eyes to harmful levels of non-ionising solar radiation (UV, Visible, and IR). Potential Harm: Permanent retinal damage, energy in harmful wavelengths,	The PPE incorporates a specialized polymer solar filter designed and verified to absorb/reflect the majority of energy in harmful wavelengths,	Primary Evidence: ICS Test Reports T18671-01-5 & T18671-01-7, confirming full compliance with EN ISO 12312-2:2015.

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3.9.2	Ionising radiation	No. The product is not designed to protect against ionising radiation (e.g., X-rays, gamma rays).	photokeratitis, thermal injury, blindness.	N/A	N/A
3.10 & 3.11	Protection against hazardous substances/biological agents; Diving equipment	No. The product is not designed to protect against these risks.	N/A	N/A	N/A

Appendix 1: Rationale for Product Service Life

Reference: EHSR 2.4 - PPE subject to ageing

A maximum service life of 3 years from the date of manufacture has been established for the EclipsePro Series solar eclipse glasses. This control measure was determined through a comprehensive risk assessment that concluded a fixed expiry date is the most effective method to mitigate risks associated with material degradation and foreseeable use patterns. The assessment is based on the following key factors:

1. Material Degradation Mechanisms: The primary safety component, the solar filter film, is an aluminized polymer. While stable under ideal conditions, its long-term integrity can be compromised by:

- **Physical Damage:** Scratches, pinholes, creases, and delamination of the metallic coating are the most significant risks. Such damage, which can be microscopic, compromises the filter's optical density and allows unsafe levels of solar radiation to pass through. The probability of such damage occurring increases significantly over time with handling and non-ideal storage.
- **Environmental Factors:** Although the materials are selected for durability, prolonged exposure to uncontrolled environments (e.g., high humidity in a basement, temperature cycles in a car) can accelerate the degradation of the filter's metallic coating and weaken the paperboard or plastic frame.
- **Conclusion:** The 3-year timeframe represents a conservative estimate of the period during which the materials can be expected to fully maintain their protective properties under a wide range of reasonably foreseeable storage conditions.

2. Foreseeable Use and Human Factors: The intended use of solar eclipse glasses involves infrequent use separated by long storage periods.

- **User Profile:** The average user is not an expert in optical safety and cannot be expected to reliably detect subtle but critical filter degradation after years of storage.
- **Risk Mitigation:** Relying solely on user inspection is insufficient. A simple, unambiguous expiry date ("Do not use if more than 3 years old") is a more robust and error-proof control measure. It removes the burden of complex assessment from the end-user.

3. Industry Best Practice and Authoritative Guidance:

- The 3-year service life is a conservative and widely accepted practice among reputable manufacturers of ISO 12312-2 compliant solar viewers.
- This practice aligns with the safety-first principle promoted by astronomical bodies like the American Astronomical Society (AAS) and NASA, which emphasize that filters must be free of any damage. An expiry date institutionalizes this caution.

Conclusion: The 3-year service life is a risk-based control measure designed to provide the highest level of assurance for user safety. This is supplemented by the instruction for users to inspect the glasses for any visible damage before every use.