# Technical File

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**Revision:** Rev. 1.0.
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| Revision | Date | Author | Description Of Change |
|---|---|---|---|
| 1.0 | 11/11/2025 | M. Grāvītis | This document supersedes `TF-SG-ECL-001`. It consolidates all EclipsePro product lines... |

**Product:** EclipsePro Series Solar Eclipse Glasses

**Manufacturer:** SIA “Gravitis Enterprise Limited"

**Manufacturer Address:** Lauku iela 7-4, Cēsis, LV-4101, Latvia

**Regulation:** (EU) 2016/425, Category II PPE

**Standard:** EN ISO 12312-2:2015(E)

**Email:** support@absoluteeclipse.com

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# 1. COVER LETTER

## Manufacturing Sites:

- Cangnan County Qiwei Craft Co., Ltd., Industrial Zone, Cangnan County, Wenzhou City, Zhejiang Province, China 325800
- SIA Gravitis Enterprise Limited, Lauku iela 7-4, Cēsis, LV-4101, Latvia

In accordance with Regulation (EU) 2016/425 Article 8(3), SIA Gravitis Enterprise Limited shall keep this technical documentation and the EU Declaration of Conformity for a period of 10 years from the date the PPE is placed on the market.

# 2. PRODUCT DESCRIPTION

This Technical File covers the EclipsePro Series of solar viewing products, a range of Personal Protective Equipment (PPE) designed for the safe, direct observation of the sun.

All products described herein are Category II PPE in accordance with Regulation (EU) 2016/425 and are designed to meet all requirements of the harmonised standard EN ISO 12312-2:2015(E). The intended use for all models is to provide protection for the user's eyes against harmful solar radiation during direct viewing of a solar eclipse.

The EclipsePro Series encompasses three distinct product lines:

## 2.1 EclipsePro Paper Series

This product line consists of solar eclipse glasses constructed from 250g/m² C1S paperboard. It serves as the standard, highly customizable model.

*Figure 2.1: Representative base model of the EclipsePro Paper Series.*

**Design Variants:**
The Paper Series is available in multiple fabrication variants which affect the overall dimensions and eye-opening shape, though the core protective filter remains identical. These variants are detailed in the attached technical drawing package (`SEG-TDP-001-RevB.pdf`) and include:

- **Base Shape** (Drawing: `SEG-FAB-001`)
- **Narrow Shape** (Drawing: `SEG-FAB-002`)
- **Eye Hole Variant B** (Drawing: `SEG-VAR-001`)

*Note: The image above illustrates the fundamental construction of the Base Shape. All variants maintain full compliance with the safety requirements of EN ISO 12312-2. Cosmetic artwork applied to the frames varies but does not alter the protective structure, as detailed in Section 3.3.*

## 2.2 EclipsePro Plastic Series

This product line consists of a family of durable, injection-molded solar viewing devices. While all models utilize the same certified solar filter, they feature distinct designs and functionalities.

### 2.2.1 Model: EGP-FIT (Oversized Fit-Over)

A single-piece frame with an oversized design and large lens area, engineered to be worn comfortably over most prescription glasses.

### 2.2.2 Model: EGP-MOD (Modular Magnetic System)

A two-part system consisting of a base frame with non-protective clear plano lenses and interchangeable front attachments. The attachments connect securely via magnets. The product is supplied with one solar filter attachment (EN ISO 12312-2) and one standard sunglass attachment (EN ISO 12312-1).

### 2.2.3 Model: EGP-CLP (Clip-On)

A frameless device consisting of two solar filter lenses joined by a spring-loaded clip mechanism, designed to attach directly to the nose bridge of a user's existing prescription eyewear.

### 2.2.4. Model: EGP-GLW (Glow-in-the-Dark)

This product line is constructed from a durable, injection-molded polypropylene homopolymer. It serves as a more robust model with a fixed, standardized design, offering enhanced reusability.

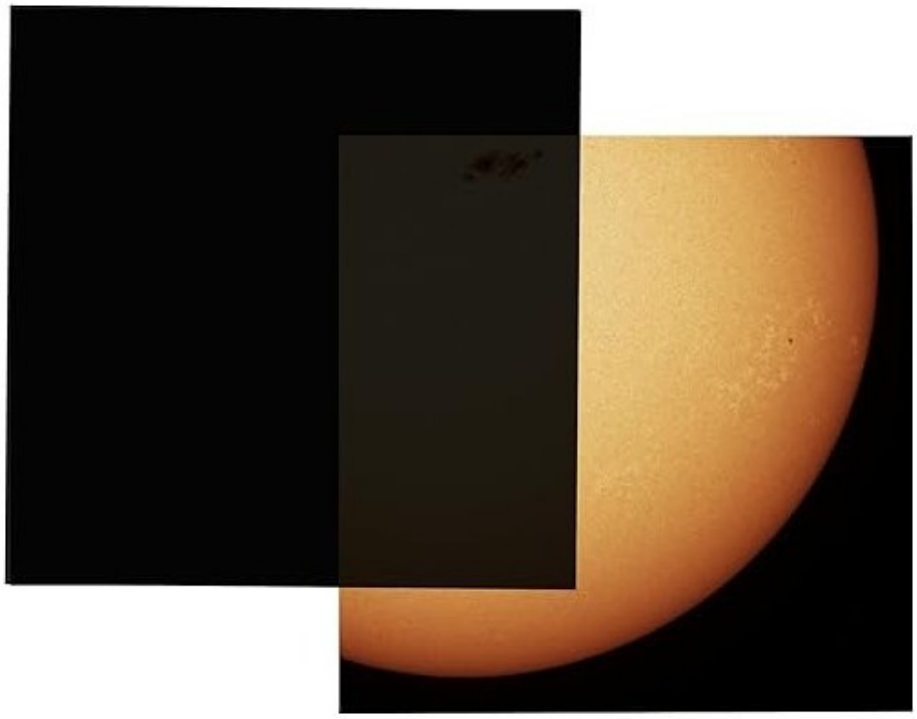
*Figure 2.2: Representative model of the EclipsePro Plastic Series.*

*Note: The image above illustrates the fundamental construction and fixed form factor of the EclipsePro Plastic Series EGP-GLW. It is shown without markings for illustrative clarity. Cosmetic finishes or pad-printed branding may vary but do not alter the protective structure, as detailed in Section 3.3 of this file.*

## 2.3 EclipsePro Filter Sheet

### 2.3.1 Model: EFS-SHT (Filter Sheet)

Supplied as a standalone component for custom applications. Its intended use requires integration by the end-user into a suitable frame or viewing device that completely shields the eyes from all peripheral sunlight.



## 2.4 Equivalency of Protection

While the models differ in frame material and durability, both the Paper Series and the Plastic Series provide the identical level of protection against harmful solar radiation. Both lines utilize independently certified solar filter and are fully compliant with all safety performance requirements of EN ISO 12312-2:2015.

# 3. DESIGN AND MANUFACTURING INFORMATION

## 3.1 Technical Drawings and Specifications

This section details the design specifications for all product lines within the EclipsePro Series. Each product and its significant variants are controlled by a dedicated Technical Drawing Package (TDP) as listed below.

### 3.1.1 EclipsePro Paper Series

- **Document Reference:** SEG-TDP-001-RevB.pdf
- **Status:** FOR NOTIFIED BODY SUBMISSION
- **Drawing Package Contents:**
    - SEG-ASSY-001: Assembly Drawing
    - SEG-MRK-001: Marking Specification
    - SEG-FAB-001: Fabrication - Base Shape
    - SEG-FAB-002: Fabrication - Narrow Shape
    - SEG-VAR-001: Fabrication - Base Shape - Eye Hole Variant B
- **Key Dimensions (from Technical Drawings):**
    - Overall Dimensions (Base Shape): 415mm width × 145mm height
    - Frame Thickness: 300g/m² cardboard
- **Packaging Specifications:**
    - PKG-PAPERSERIES-5PK-OUTER-001: Artwork for 5-Unit Pack
    - PKG-PAPERSERIES-10PK-OUTER-001: Artwork for 10-Unit Pack

### 3.1.2 EclipsePro Plastic Series

The Plastic Series consists of several models with unique designs. Each is controlled by its own drawing package.

#### *3.1.2.1 Model: EGP-FIT (Oversized Fit-Over)*

- **Document Reference:** TDP-SG-EGP-FIT-RevA.pdf
- **Status:** FOR NOTIFIED BODY SUBMISSION
- **Drawing Package Contents:**
    - EGP-FIT-MRK-001: Marking Specification
    - EGP-FIT-ASSY-001: Assembly Drawing
    - EGP-FIT-FAB-001: Fabrication - Main Frame
- **Key Dimensions (from Technical Drawings):**
    - Overall Width: [e.g., 155mm] # TODO
    - Frame Height: [e.g., 52mm] # TODO
    - Frame Thickness: [e.g., 2.2mm (nominal)] # TODO
- **Packaging Specification:**
    - PKG-PLASTIC-SERIES-1PK-OUTER-001: Artwork for Single Unit Packaging

#### *3.1.2.2 Model: EGP-MOD (Modular Magnetic System)*

- **Document Reference:** TDP-SG-EGP-MOD-RevA.pdf
- **Status:** FOR NOTIFIED BODY SUBMISSION
- **Drawing Package Contents:**
    - EGP-MOD-MRK-001: Marking Specification (Base Frame & Attachments)
    - EGP-MOD-ASSY-001: Assembly Drawing (Full System)
    - EGP-MOD-FAB-001: Fabrication - Base Frame & Clear Lenses
    - EGP-MOD-FAB-002: Fabrication - Solar Filter Attachment
    - EGP-MOD-FAB-003: Fabrication - Sunglass Attachment
- **Key Dimensions (from Technical Drawings):**
    - Base Frame Width: [e.g., 145mm] #TODO
    - Magnetic Attachment Height: [e.g., 48mm] #TODO

#### 3.1.2.3 Model: EGP-CLP (Clip-On)

- **Document Reference:** TDP-SG-EGP-CLP-RevA.pdf

•**Status:** FOR NOTIFIED BODY SUBMISSION

•**Drawing Package Contents:**

•EGP-CLP-MRK-001: Marking Specification

•EGP-CLP-ASSY-001: Assembly Drawing

•**Key Dimensions (from Technical Drawings):**

•Overall Width (Assembled): [e.g., 130mm]

•Lens Diameter: [e.g., 50mm]

#### *3.1.2.4 Model: EGP-GLW (Glow-in-the-Dark)*

•**Document Reference:** TDP-SG-EGP-GLW-RevA.pdf

•**Status:** FOR NOTIFIED BODY SUBMISSION

•**Drawing Package Contents:**

•EGP-GLW-MRK-001: Marking Specification

•EGP-GLW-ASSY-001: Assembly Drawing

•EGP-GLW-FAB-001: Fabrication - Main Frame

•**Key Dimensions (from Technical Drawings):**

•Overall Width: 140mm

•Frame Height: 49mm (front view)

•Frame Thickness: 2.0mm (nominal)

### 3.1.3 EclipsePro Filter Sheet

•**Document Reference:** TDP-SG-EFS-SHT-RevA.pdf

•**Status:** FOR NOTIFIED BODY SUBMISSION

•**Drawing Package Contents:**

•EFS-SHT-MRK-001: Marking Specification for Sheet & Packaging

•EFS-SHT-FAB-001: Fabrication Dimensions & Tolerances

•**Key Dimensions (from Technical Drawings):**

•Sheet Dimensions: [e.g., 210mm x 297mm]

•Film Thickness: [e.g., 0.12mm]

### 3.1.4 Critical Design Requirements (Applicable Across All Relevant Products)

• **Filter Coverage:** Minimum 3mm overlap of the solar filter around all eye openings in spectacle-style products.

• **Tolerances:** Unless otherwise specified in the respective TDP, general tolerances are: Linear ±0.5mm, Angular ±1°.

• **Zero Light Leakage:** All designs for finished eyewear (Paper and Plastic Series) ensure no direct light leakage around the filter edges when properly assembled and worn.

• **Structural Integrity:** Designs ensure structural integrity during normal handling forces. This includes the mechanical strength of the clip mechanism (EGP-CLP) and the magnetic holding force (EGP-MOD), which are further detailed in the EHSR.

• **Complete Eye Coverage:** All finished eyewear designs ensure full bilateral eye coverage with adequate safety margins. For the EFS-SHT, the IFU explicitly instructs the user on achieving this requirement.

## 3.2 Manufacturing Process Specifications

### 3.2.1 Primary Manufacturing & Sub-Assembly (Cangnan County Qiwei Craft Co., Ltd., China)

This stage covers the fabrication of key components and sub-assemblies for all product lines.

- **Environmental Controls:** Temperature: 20-25°C (±2°C); Humidity: 45-65% RH; Clean work environment with filtered air supply.
- **Common Process Steps:**
    1. **Material Receiving & Inspection:** Verification of all incoming raw material certificates (polymers, filter film, cardboard, hardware) and dimensional checks against technical drawings.
    2. **Solar Filter Processing:** Die-cutting of certified solar filter film to the specific lens shapes required for all models.
- **Product Line Specific Steps:**
    1. **For Paper Series:** Automated lamination of filter lenses to die-cut paperboard frames.
    2. **For Plastic Series (EGP-FIT, EGP-GLW, EGP-MOD):** Injection molding of all plastic components (frames, temples, magnetic attachments). Lamination of filter lenses into frame apertures or solar filter attachments.
    3. **For Clip-On Model (EGP-CLP):** Assembly of the bridge-and-clip mechanism. Lamination of filter lenses into the lens holders.
    4. **For Filter Sheet (EFS-SHT):** Cutting of filter film to final sheet dimensions.
- **Common Concluding Steps:**
    1. **Quality Control:** 100% automated light leak and contamination inspection for all lens/frame assemblies. Visual and dimensional inspection of molded parts and finished sheets.
    2. **QR Code Application:** Activation of the traceability system for each unit or its primary component.
    3. **Packaging:** Bulk protective packaging of all components and sub-assemblies for secure shipment to Latvia.

**3.2.2 Final Assembly, Quality Control & Packaging (SIA Gravitis Enterprise Limited, Latvia)**

This stage covers the final assembly, inspection, and retail packaging of all finished goods.

- **Process Steps:**
    1. **Incoming Inspection:** 5% statistical sampling of all components received from the primary assembly stage to verify quality and specifications.

2. **Final Assembly & Kitting:**

    • (Paper Series): Final precision die press cutting and folding of frames per technical drawings.

    • (Plastic Series - EGP-FIT, EGP-GLW): Assembly of temples to main frames using hinge screws.

    • (Plastic Series - EGP-MOD): Kitting of the base frame with the solar filter attachment and the sunglass attachment into the final retail package.

    • (Plastic Series - EGP-CLP): Final functional testing of the spring mechanism.

    • (Filter Sheet - EFS-SHT): No assembly required. Proceed directly to packaging.

3. **Final Quality Control:** Director-supervised physical inspection of a statistical sample from every batch. Checks include cosmetic defects, sharpness, structural integrity, and verification of correct model configuration and markings.

4. **Packaging & Dispatch:** Final retail packaging of each product with all required, model-specific documentation (IFU leaflet) and labeling.

## 3.3 Control of Optional Decorative Artwork and Branding

This section defines the controlling principles for any and all decorative artwork, customer branding, or promotional markings applied to the EclipsePro Series products. These elements are distinct from and subordinate to the mandatory regulatory markings specified elsewhere in this Technical File.

The application of any such artwork is permitted only if it adheres to the following requirements:

1. **Positional Constraints:**

    • The artwork shall be positioned so that it does not obscure, conflict with, or reduce the legibility of any mandatory regulatory markings as defined in the Marking Specification (e.g., SEG-MRK-001).

    • A non-violable clear space of at least 5mm shall be maintained around all mandatory markings.

2. **Material Control:**

    • All materials used to apply decorative artwork must have documented evidence of compliance with the same EU safety standards as the base product materials.

    • The vegetable oil-based inks used for such artwork shall be from the set verified by SGS test reports SHAEC24022975101, ...103, ...105, and ...107, which are included in this Technical File.

    • Any other materials (e.g., alternative inks, hot stamping foils) may only be used after the manufacturer has obtained and filed complete test reports from an accredited laboratory demonstrating equivalent compliance with REACH and other applicable EU safety standards.

3. **Manufacturer Responsibility:**

    • The legal manufacturer, SIA "GRAVITIS ENTERPRISE LIMITED," bears full responsibility for ensuring any product placed on the market, including all decorative elements, is fully compliant with these controlling principles and Regulation (EU) 2016/425.

# 4.0 INSTRUCTIONS FOR USE (IFU) & MARKING STRATEGY

This section defines the hierarchical information strategy for the entire EclipsePro Series, ensuring full compliance with Regulation (EU) 2016/425. The strategy provides complete and accessible information to the end-user via four distinct layers: on-product marking, on-packaging marking, a physical Instructions for Use (IFU) leaflet, and a digital platform. The approach is adapted for the unique physical characteristics and intended use of each product line.

## 4.1 Marking & Information Location Matrix

The physical IFU leaflet serves as the primary, comprehensive guide for all products, repeating and explaining information found elsewhere. The location of mandatory information varies by product line due to differences in physical construction and available surface area.

| Information / Marking | EclipsePro Paper Series | EclipsePro Plastic Series (All Models) | EclipsePro Filter Sheet |
|---|---|---|---|
| **CE Mark & Notified Body Nr.** | On-Product & IFU Leaflet | On-Product & IFU Leaflet | On-Packaging & IFU Leaflet |
| **Standard (EN ISO 12312-2)** | On-Product & IFU Leaflet | On-Product & IFU Leaflet | On-Packaging & IFU Leaflet |
| **Manufacturer Name & Address** | On-Product & IFU Leaflet | On-Packaging & IFU Leaflet | On-Packaging & IFU Leaflet |
| **Product Model Identification** | On-Product & On-Packaging | On-Packaging & IFU Leaflet | On-Packaging & IFU Leaflet |
| **EU Type-Examination Statement** | On-Product & On-Packaging | On-Packaging | On-Packaging |
| **QR Code & Unique Serial Number** | On-Product | On-Packaging | On-Packaging |
| **Use By Date** | Provided Digitally (via QR) | Provided Digitally (via QR) | Provided Digitally (via QR) |
| **Storage Conditions** | IFU Leaflet Only | IFU Leaflet Only | IFU Leaflet Only |

## 4.2 Justification for Differentiated Marking Strategy

The variation in marking locations is a necessary adaptation to the fundamental differences between the product lines.

• **EclipsePro Paper Series:** Constructed from flat, wide paperboard, which provides ample surface area for the application of all mandatory markings directly onto the product.

• **EclipsePro Plastic Series:** The temple arms of the injection-molded frames are narrower and feature curved profiles. This geometry makes it technically infeasible to legibly and permanently print extensive text (such as the full manufacturer address). In accordance with Regulation (EU) 2016/425 for space-constrained products, this information is moved to the primary packaging and accompanying IFU.

• **EclipsePro Filter Sheet:** As a flexible, transparent film component, applying permanent, legible markings directly onto the filter surface without compromising the optical viewing area is not feasible. Therefore, all mandatory markings are placed on the protective primary packaging and within the IFU.

## 4.3 Instruction Documentation (Physical & Master)

To ensure all users have access to critical and model-specific safety information, instructions are provided in multiple formats. Every retail unit includes a printed Instructions for Use (IFU) leaflet with comprehensive safety warnings, usage instructions, and storage conditions tailored to that specific product.

• **Languages:** English, German, French, Italian, Spanish, Portuguese, and Dutch.

• **Document Control:** For full traceability, each leaflet is printed with its unique document number, revision, and release date. The document identifiers correspond to the specific product model:

- **Paper Series:**
  - `IFU-SG-PAPER-SERIES-RevA #TODO`
- **Plastic Series:**
  - `IFU-SG-EGP-FIT-RevA` (For Oversized Fit-Over model) # TODO
  - `IFU-SG-EGP-MOD-RevA` (For Modular Magnetic System) # TODO
  - `IFU-SG-EGP-CLP-RevA` (For Clip-On model) # TODO
  - `IFU-SG-EGP-GLW-RevA` (For Glow-in-the-Dark model) # TODO
- **Filter Sheet:**
  - `IFU-SG-EFS-SHT-RevA # TODO`

• **Digital Instructions for Use (IFU)**: The complete and most up-to-date version of the instructions for all models is always digitally available online via the traceability system.

## 4.4 Digital Information System (QR Code & Website)

The traceability and shelf-life information system is entirely digital.

• **Access:** Each unit (or its packaging) is assigned a unique serial number, accessible via a scannable QR code and as a human-readable number. Users can access product-specific data by scanning the code or by manually entering the serial number at verify.absoluteeclipse.com.

• **Information Provided:** The system provides the product’s official Use By date, its manufacturing date, and a link to the complete digital IFU and EU Declaration of Conformity (DoC). This system is detailed in Section 5.1.

## 4.5 Regulatory Compliance Confirmation

This multi-layered and differentiated information strategy ensures full compliance with Regulation (EU) 2016/425, Article 8, and Annex II. The justified approach for each product line guarantees that all mandatory information remains clear, accessible, and permanently available to the end-user throughout the product's lifecycle.

# 5. PRODUCT IDENTIFICATION & TRACEABILITY

## 5.1 Traceability System Specification

**Identification Method:** Per-Unit Serial Number
**Example:** 9005585

The traceability system is based on a unique serial number assigned to every individual unit, replacing traditional batch marking. This serial number is accessible as both a scannable QR code and a human-readable number. Users can access the product's unique information by either scanning the QR code or by manually entering the serial number at **verify.absoluteeclipse.com**.

**QR Code and Serial Number Location:**

- **EclipsePro Paper Series:** The unique QR code and serial number are applied directly to each individual product frame.
- **EclipsePro Plastic Series:** Due to on-product space constraints, the unique QR code and serial number are applied to the primary retail packaging.

**Each unique serial number provides access to a digital record containing:**

- Manufacturing Date and the official **Use By Date**.
- Product model variant identification.
- Link to the complete digital Instructions for Use (IFU) and EU Declaration of Conformity (DoC).
- Verification of key quality control checks.
- Company contact information for compliance documentation.
- Material traceability reference numbers.

**Traceability Chain:**
The system creates a verifiable link from raw material supplier batches through internal production records to the unique serial number assigned to each finished product. This complete chain is stored digitally for the required 10-year retention period.

This system ensures individual product traceability and satisfies the information and traceability requirements of Regulation (EU) 2016/425 Article 8(5).

# 6. MATERIALS DOCUMENTATION & RISK ASSESSMENT

## 6.1 Complete Material Specifications with Test Reports

All materials used in the EclipsePro Series solar eclipse glasses have been selected for innocuousness and are verified for compliance with applicable EU safety regulations through test reports from internationally accredited laboratories.

A complete and detailed matrix of all materials, their specifications, manufacturers/suppliers, and corresponding compliance test reports is provided in the following controlled document:

**TF-SG-ECL-001-AnnexB: Material Compliance Summary**

This annex serves as the primary reference for all material compliance evidence and supersedes the detailed lists previously in this section.

**Note on Test Report Naming and Scope:** The solar filter material is identical across all product variants. The test reports from ICS Laboratories (series T18671) confirm its compliance. Some reports may refer to internal development product names (e.g., "Absolute Eclipse Glow in the Dark Solar Glasses"); however, they document the testing of the final, certified filter component used in all EclipsePro Series models. The phosphorescent pigment used for the "glow" effect in the plastic series is a purely cosmetic additive and has been independently verified for safety and innocuousness.

## 6.2 Essential Health and Safety Requirements (EHSR) Assessment

In accordance with Annex II of Regulation (EU) 2016/425, a comprehensive and systematic risk assessment has been conducted to identify all relevant hazards for the EclipsePro Series Solar Eclipse Glasses. The harmonised standard **EN ISO 12312-2:2015** has been used to presume conformity with the relevant EHSRs it covers.

The complete, detailed analysis demonstrating compliance with each applicable requirement is documented in the formal checklist attached to this Technical File:

> **Primary Record: Annex A: Essential Health and Safety Requirements (EHSR) & Risk Assessment Checklist (Document ID: TF-SG-ECL-001-AnnexA)**

This Annex serves as the definitive record of the EHSR assessment.

### Summary of Key Risks and Control Strategies

The assessment confirmed that the primary risks associated with this type of PPE have been fully addressed through a multi-layered control strategy:

- **Hazard: Non-ionising Solar Radiation.**
  - **Control:** Use of a specialized polymer solar filter, certified by an accredited laboratory (ICS Laboratories) to meet all spectral transmittance requirements of EN ISO 12312-2:2015.
- **Hazard: Chemical Hazards from Materials.**
  - **Control:** All constituent materials (polypropylene frame, paperboard frame, inks, foils, adhesive) have been selected for innocuousness and their compliance verified against EU regulations (e.g., REACH SVHC) through test reports from accredited laboratories (SGS, Sinolight).
- **Hazard: Light Leakage and Physical Integrity.**
  - **Control:** Robust frame designs that ensure full eye coverage and a minimum 3mm filter overlap are documented in technical drawings. Risks are further mitigated by automated manufacturing controls (e.g., 100% light leak inspection) and final quality control procedures.
- **Hazard: Misuse and Lack of Information.**
  - **Control:** Provision of clear, permanent on-product markings and a comprehensive, multi-language printed Instructions for Use (IFU) leaflet with every unit, as detailed in Section 4 of this Technical File.

### Assessment Conclusion

All applicable Essential Health and Safety Requirements of Annex II are satisfied through the combination of compliant design, verified materials, controlled manufacturing processes, and comprehensive user information. All identified risks have been reduced to an acceptable level, ensuring the product is safe for its intended use.

## 6.3 Material Risk Assessment Conclusion

Complete Material Compliance Matrix:

| Material / Component | Governing Evidence (Test Report ID) | Verified Standard / Regulation | Status |
|---|---|---|---|
| **Solar Filter Film** | T18671-01-5 & T18671-01-7 (ICS Labs) | EN ISO 12312-2:2015 | ✅ PASS |
| **Paper Frame** | 2025020014 (Sinolight) | GB/T 24999-2018 | ✅ PASS |
| **Plastic Frame (Base Resin)** | Formosa Product Safety Certificate | REACH SVHC | ✅ PASS |
| **Plastic Frame Additive (Glow Powder)** | RT20250430004 (DGRTTS MSDS) | GHS Chemical Safety | ✅ PASS |
| **Printing Inks (CMYK)** | SHAEC24022975101 / 103 / 105 / 107 (SGS) | EU Chemical Safety (Mineral Oil) | ✅ PASS |
| **Adhesive** | CANEC25014912901 (SGS) | REACH SVHC | ✅ PASS |
| **Hot Stamping Foil** | TAOEC25006916401 (SGS) | REACH Phthalates | ✅ PASS |

**Risk Assessment Conclusion:** All materials used in the EclipsePro Series have been tested by internationally accredited laboratories (SGS, Sinolight, ICS). The results confirm full compliance with the relevant Essential Health and Safety Requirements of Regulation (EU) 2016/425, primarily **Regulation (EC) No 1907/2006 (REACH)** for chemical safety and **EN ISO 12312-2:2015** for the solar filter's performance and material innocuousness.

# 7. QUALITY CONTROL PROCEDURES

## 7.1 Enhanced Quality Control with Automated Systems

China Manufacturing - Automated Quality Control:

1. Position Control System:

- Automatic lamination machine with precision film positioning
- Tolerance: ±1mm maximum deviation
- Action: Machine stops when tolerance exceeded
- Resolution: Operator repositioning required before restart

2. Contamination Detection System:

- Automated inspection of frame surface cleanliness before filter application
- Action: Machine stops when contamination detected
- Protocol: Cleaning required before production continues

3. Light Leak Detection System:

- Coverage: 100% automated inspection of each completed unit
- Tolerance: 0% light transmission (complete seal required)
- Action: Automatic rejection and segregation of defective units

Statistical Quality Sampling:

- Frequency: 5% of production with minimum 10 units per batch
- Inspection Checklist:
    - Filter integrity (no scratches, holes, or delamination)
    - Frame condition (no cracks or structural damage)
    - Bond quality (no separation or air bubbles)
    - Markings present and legible
    - QR code scannable and functional

Pass/Fail Criteria:

- PASS: All automated systems confirm compliance, visual inspection confirms no safety-affecting defects

- FAIL: Any automated system failure or visual defect affecting safety = batch investigation
- Critical Defect: Any filter damage = immediate batch hold and root cause analysis

Latvia Final Assembly Quality Control:

- Incoming Inspection: 5% sampling of China-manufactured components
- Process Control: Die press maintenance, operator certification, director oversight
- Final Approval: Director sign-off based on 3 solar eclipse campaigns experience
- Documentation: Digital records linked to QR traceability, 10-year retention

# 8. LIST OF APPLIED STANDARDS AND LEGISLATION

## 8.1 Applied Legislation and Key Harmonised Standard

- Regulation (EU) 2016/425: on Personal Protective Equipment (PPE).
- EN ISO 12312-2:2015(E): *Eye and face protection - ... Filters for direct observation of the sun.* Compliance with this harmonised standard provides presumption of conformity.

## 8.2 Supporting Standards and Regulations

- REACH Regulation (EC) 1907/2006: *Registration, Evaluation, Authorisation and Restriction of Chemicals* (Applied for SVHC screening).
- GB/T 24999-2018: *Coating paper and board* (Applied to the Paper Series frame).

## 8.3 Summary of Required Information & Markings

This list summarises the key information and markings applied across the product system. The exact location is defined in Section 4.1.

- CE Mark
- Notified Body Identification (Provided on packaging/IFU, not adjacent to CE mark)
- EN ISO 12312-2 standard identification
- Manufacturer & Product Identification
- Category II PPE classification
- Unique Product Identification (Per-unit QR code/serial number)
- Use By Date (Provided digitally via the QR code system)

# 9. EU DECLARATION OF CONFORMITY

Status: Prepared and ready for finalization upon successful certification

(DOC-SG-ECL-001)

Availability: Will be accessible via:

- QR code scan on each product
- Website: verify.absoluteeclipse.com
- Email request: support@absoluteeclipse.com
- Content: Declaration confirming compliance with Regulation (EU) 2016/425 and EN ISO 12312-2:2015(E)

# 10. RESULTS OF DESIGN CALCULATION

## 10.1 Technical Drawings

- **EclipsePro Paper Series:**
    - SEG-TDP-001 Rev. B - Complete Technical Drawing Package (7 sheets)
- **EclipsePro Plastic Series:**
    - SEGP-TDP-001 Rev. B – Complete Technical Drawing Package (5 sheets)

## 10.2 Material & Component Test Reports

A complete matrix of all constituent materials, their specifications, suppliers, and corresponding compliance test reports is consolidated in the following controlled document:

- **TF-SG-E-001-AnnexB: Material Compliance Summary**

This annex serves as the master list for all material-related compliance documentation and contains the full details for the frame, inks, foils, adhesives, and additives.

## 10.3 Solar Filter Certification (EN ISO 12312-2:2015)

The solar filter film used in all product variants is certified for compliance with EN ISO 12312-2:2015.

- **T18671-01-1** - Solar Filter Compliance Test Report (ICS Laboratories)
- **T18671-01-3** - Solar Filter Compliance Test Report (ICS Laboratories)

## 10.4 Regulatory & User Information Documents

- **Instructions for Use (Paper Series):**
    - SEG-IFU-Physical-001 Rev. B - Printed Instructions of Use Leaflet
- **Instructions for Use (Plastic Series):**
    - SEGP-IFU-Physical-001 Rev. B – Printed Instructions of Use Leaflet
- **EU Declaration of Conformity:**
    - DOC-SG-ECL-001-RevA - EU Declaration of Conformity

## 10.5 Packaging Artwork Specification

• **PKG-PAPERSERIES-5PK-OUTER-001 Rev. A:** Outer Carton Artwork (5-Pack)

• **PKG-PAPERSERIES-10PK-OUTER-001 Rev. A:** Outer Carton Artwork (10-Pack)

• **PKG-PLASTIC-SERIES-1PK-OUTER-001 Rev. A:** Primary Packaging Artwork (Plastic Series)

## 10.6 Supporting Documentation Summary

The complete documentation package demonstrates full regulatory compliance through:

• Technical drawing specifications with dimensional tolerances

• International laboratory testing of all materials

• Comprehensive quality control procedures

• Full traceability and marking systems

• EU regulatory compliance verification

# 11. DOCUMENT RETENTION COMMITMENT

In accordance with Regulation (EU) 2016/425 Article 8(3):

SIA Gravitis Enterprise Limited commits to keeping this technical documentation and the EU Declaration of Conformity for a period of 10 years from the date the PPE is placed on the market. This includes:

- Complete technical file and all revisions
- All supporting test reports and material certifications
- Quality control records and traceability documentation
- Manufacturing process specifications and drawings
- Declaration of Conformity and certification documentation

Document Control:

Person Responsible for Technical Documentation:
Māris Grvitis, Director
SIA Gravitis Enterprise Limited

Approved by: Māris Gravitis, Director
Date: July 14, 2025

Signature: 

Notified Body: MTIC Intercert S.r.l. 0068, Via G. Leopardi. 14 - 20123 Milan (MI) – Italy

END OF TECHNICAL FILE Rev. 2.1