



Shirley

Personal Protective Equipment Regulation (EU) 2016/425

Certificate

Module B EU Type-Examination

Manufacturer

Protech Leaded Eyewear Inc, DBA Protech Medical

1360 N Killian Drive, Lake Park, Florida 33403, USA

Product Description:

X-ray radiation protection eyewear

Product Code:

See page 2 for product codes

Technical File Reference:

523415

Harmonised Standard(s):

Not Applicable

Technical Specification:

EN 61331-1:2014; EN 61331-3:2014

Certificate Number: SH00792

Issued by: Shirley® (Notified Body No. 2895 for Regulation (EU) 2016/425)

First issue: 20 December 2021 **Date of Issue:** 20 December 2021 **Expiry:** 03 December 2024

Authorised by

C A Butcher

Certification Manager

The attached schedule of approval forms part of this certificate.

Note: The validity of this certificate can be confirmed by contacting the Issuing Office:
Shirley Technologies (Europe) Limited, Sky Business Centre, Port Tunnel Business Park, Office 13
Unit 21, Clonsaugh Business & Technology Park, Dublin 17, ROI

Tel: +353 (0) 01894 1448 **email:** info@shirley.ie **website:** www.shirley.ie





Schedule of Approval
Certificate Number: SH00792

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| First Issued: | 20 December 2021 | Page No: | 2 of 7 |
| Issue date: | 20 December 2021 | Issued by: | Shirley® (Notified Body No. 2895) |
| Expiry date: | 03 December 2024 | Shirley® ref: | SH-023658 |
| Manufacturer: | Protech Leaded Eyewear Inc, DBA Protech Medical | | |
| Technical file ref: | 523415 | | |

Shirley®, specified as a "notified body" under the terms of the Regulation (EU) 2016/425 of the European Parliament and of the Council on personal protective equipment, did undertake the relevant type approval procedures for the equipment identified below which was found to be in compliance with the relevant provisions of Annex V (Module B) of the Regulation and with the applicable essential health and safety requirements, subject to any conditions in the schedule attached hereto.

The certificate relates specifically to the PPE items described and depicted in the manufacturer's Technical File, copies of which are held by the manufacturer and Shirley®, and not to any other items.

The certificate remains valid unless cancelled or revoked, provided the conditions in the attached schedule are complied with and the equipment remains satisfactory in service.

This Certificate cancels and replaces Certificate No. 523548/1 dated 03 December 2019.

Description of product

X-ray radiation protection eyewear consisting of:

Glasses

| | | | | |
|---------------------|---------------------|----------------------|-----------------------|----------------|
| 42 Fitover; | 90 Fitover; | 53 Wrap; | 53 Economy Wrap; | 553s Metalite; |
| 557s Metalite; | 661 Metalite; | 662s Metalite; | 70s Astroflex; | 98 Superlite; |
| 99 Alumilite; | 99 Ultralite; | 99 Ultralite Small; | 99 Ultralite Bridge; | 9935 Reg; |
| 9935 LG; | 9941 Ultralite; | 994153 Ultralite SM; | 9941 UL w Nosepad; | Classic Metal; |
| Modern Metal; | Petite Metal; | Metal Aviator; | Vader; | Comet; |
| Cocoons Flexfit LG; | Cocoons Flexfit XL; | Tugga Baby; | Kai; | Bravo; |
| Waikiki; | Tiki; | Dockside; | Jesse; | Reese; |
| Brazen; | Flex Finesse; | Rabid; | Airdrop Mnp (53); | Carbon Plate; |
| Cross Step (52); | Crosslink Mnp (55); | Five Squared (54); | Jupiter Squared (56); | Mainlink (57); |
| Metal Plate (53); | Metal Plate (55); | Frogskin (rx) (54); | Trillbe X (rx) (52); | Tincup (52) |
| Straightlink (58); | Tincup (54); | Truss Rod (53); | Truss Rod (55); | Twoface (60); |
| Leaders; | 3016; | 3534; | 4105; | 4165F Justin; |
| 4195; | 5228; | 5268; | 6356; | 6373M; |

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|-------------|-------------|-------------|--------------|---------------|
| 7031; | 7131; | 8352; | 8901; | Daddy-O 2016; |
| Horus; | Rydon; | Zyon; | Boss; | Brick; |
| Contour; | P-17; | RE-CRUIS; | RE-ARBI; | RE-CONTO; |
| RE-PILOT; | RE-9941M; | RE-FGUARDE; | RE-MALIB; | RE-ARDENT; |
| RE-MAKO; | RE-ARBI; | RE-XGUARD; | RE-OGUARD; | RE-ONYX; |
| RE-RAZER; | RE-RENEG; | RE-LEADMAX; | RE-SKYLAR; | RE-AIRB; |
| RE-ASPEN; | RE-FGUARDA; | RE-ELON; | RE-ADMIN; | RE-CENT; |
| RE-FGUARDB; | RE-ENTERP; | RE-CHALL; | RE-SENTINEL; | RE-EDGE; |
| RE-HORNET; | RE-CIRCUIT; | RE-RIDER; | RE-STRYKER; | RE-MAJOR; |
| RE-FLOW | | | | |

Masks

450FPM; 400PSM

Available in the following materials:

Heavy duty protective eye lenses 0.75 mm Pb L.E options:

65 mm RWB-46 400B C/T: 2.5 mm
73 mm RWB-46 600B C/T: 2.5 mm
73 mm RWB-46 800B C/T: 2.5 mm
80 mm RWB-46 400B C/T: 2.5 mm

Heavy duty protective eye lenses 0.50 mm Pb L.E. options:

4B65; Main Lens
4B65; Main Lens
Progressive 4B +2.5; Main Lens
Side Shields

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Manufacturers Technical Specification

The manufacturer's Technical Specification for the end use of X-Ray Protective Clothing and accessories was based on testing according to EN 61331-1:2014. Product design is based on EN 61331-3:2014.

The suitability of this specification was checked with respect to the Essential Health and Safety Requirements of Regulation (EU) 2016/425 and was found to address the requirements for this end use.

Limitations of Use

- Usage, maintenance and storage as per manufacturer's instructions.

Observations

- Not Applicable.

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Approval Documents

- Material test report Nos. 6253817; 2018110109_1

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Manufacturer: **Protech Leaded Eyewear Inc, DBA Protech Medical**

Technical file ref: **523415**

Terms and Conditions associated with the issue of this EU Type-Examination Certificate

1. This certificate is issued subject to Shirley®'s standard terms of business, available from our website.
2. Production is limited to the site(s) listed in the manufacturer's Technical File, copies of which are held by the manufacturer and Shirley®, and not to any other production site(s).
3. The client must implement appropriate changes as notified by Shirley®.
4. The client must ensure the certified product is representative of the ongoing manufactured product.
5. The client must make provision for access to relevant documents and records.
6. The client must investigate complaints associated with the certified products. Records of such complaints, and actions taken, must be kept by the client and made available to Shirley® when requested.
7. The client must only make claims consistent with the scope of certification,
8. The client must not make any misleading or unauthorised comments regarding the certified product or the certification body.
9. The client must upon suspension, withdrawal, or termination of certification discontinue the use of all advertising matter that contains any reference thereto and take action to return this certificate to Shirley®.
10. The client must comply with the requirements for the use of the notified body number as detailed below.
11. Any change to the product or quality manual / quality plan shall be immediately notified to Shirley®.
12. This certificate is issued in the English language only. It is the responsibility of the Manufacturer / Authorised Representative to obtain and supply language versions acceptable to the country where the product is to be sold. This certificate remains the property of Shirley® and will be withdrawn if any of the conditions attached to its issue are not complied with.
13. The EC mark consists of the letters 'CE', in the form given in Annex II of Regulation (EC) No 765/2008 and for category III PPE, followed by the number of the notified body involved in production control monitoring (Module C2 or D).
14. This certificate does not authorise the use of the Mark of Conformity (the 'CE mark'), which may only be affixed to the above type approved equipment and a Manufacturer's Declaration of Conformity issued when Module C2 or D of the Regulation is fully complied with and controlled by a written agreement with a notified body.

Use of Notified Body Number

1. The Notified Body Number must only be used
 - a. In direct association with products or systems covered by this Type-Examination Certificate.
 - b. by holder(s) of the Certificate.
2. Use of Shirley® Notified Body Number does not extend to other companies which are:
 - a. part of the same corporate group as the Certificate holding company: or
 - b. named in a Certificate, for example as a supplier.
3. Particular care must always be taken to avoid the association of the Shirley® Notified Body Number with other products or systems or schemes and with claims or information not contained in the Shirley® document.

If any of the above requirements are not met Shirley® will seek to suspend, withdraw or terminate this certificate.

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END OF SCHEDULE

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