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: 15 January 2025 Expiry: 03 December 2029

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, Clonshaugh Business & Technology Park, Dublin 17, ROI

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

ISO 17065 IVNAB ACCREDITED PRODUCT CERTIFICATION DETAILED ON SCOPE REG NO. 0033

Schedule of Approval
Certificate Number: SH00792

First Issued:	**20 December 2021**	**Page No:**	**2 of 7**
Issue date:	**15 January 2025**	**Issued by:**	**Shirley® (Notified Body No. 2895)**
Expiry date:	**03 December 2029**	**Shirley® ref:**	**SH-031295**

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.

Description of product

X-ray radiation protection eyewear consisting of:

Glasses

RE-90	RE-42	RE-FGUARDA	RE-FGUARDB	RE-70S	RE-COMET
RE-COM	RE-OG220	RE-XGUARD	RE-53	RE-53E	RE-MALIB
RE-RETRO	RE-002	RE-003	RE-007	RE-008	RE-553
RE-553S	RE-557S	RE-662S	RE-98	RE-99	RE-99R
RE-99SM	RE-9941	RE-994153	RE-9941A	RE-BABY	RE-AIRB
RE-CENT	RE-CIRC	RE-ONYX	RE-MAKO	RE-RAZER	RE-TBABY
RE-VAL	RE-EDGE	RE-RYK	RE-ATLAS	RE-ASPEN	RE-LOTUS
RE-LEG	RE-JUN	RE-LOND	RE-ATH	RE-LAT	AB-DOCK
AB-JES	AB-KAI	AB-TIKI	AB-WAI	CO-ALE	CO-ARA
CO-BFIN	CO-BRD330	CO-BRD320	CO-FER	CO-OCR4	CO-SEA
CO-SUL	CO-TALY	CO-TYB	LBT-MX30S	LBT-MX30	LBT-MX31S
LBT-BIKER	N-7116	N-7117	N-7118	N-7245	N-7284

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N-7286	N-ADR	N-BR	N-BRF	N-BRS	N-MAV	N-PRMR
N-RABID	N-WAVE	OA-CROSSZ	OA-FIVESQ	OA-HOL	OA-JUP	OA-LITE
OA-STRGHT	OA-TRILL	RB-2016	RB-3534	RB-4105	RB-4165	RB-4181
RB-7074	WX-AIRR	WX-BRICK	WX-BOSS	WX-CON	WX-PO17	GG-0372
GG-0752	GG-0758					

Masks

450FPM	400PSM	300GOG	350FLP

Available in the following materials:

Plano Lead Glass Lenses:

CT ≥2.4 mm with a Lead Equivalence of 0.50 mmPb at 150 kV
CT ≥2.4 mm with a Lead Equivalence of 0.75 mmPb at 150 kV

Semi-finished Lead Glass Lenses:

CT ≥2.4 mm with a Lead Equivalence of 0.50 mmPb at 150 kV
CT ≥2.4 mm with a Lead Equivalence of 0.75 mmPb at 150 kV

Progressive Lead Glass Lenses:

CT ≥2.4 mm with a Lead Equivalence of 0.50 mmPb at 150 kV

Lead Acrylic Light-duty Protective Mask:

With an Attenuation Ratio ≥ 2 at 120 kV

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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. 2023070331-1

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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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