Personal Protective Equipment Regulations (Regulation 2016/425 as brought into UK law and amended)

Quality Assurance Certificate

Module D

Manufacturer

Protech Leaded Eyewear, Inc. DBA Protech Medical

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

Scope:

UKCA Marking of X-Ray Protective Clothing, Eyewear and Accessories

Certificate Number: 54180

Issued by: BTTG® (Approved Body No. 0338 for Regulation 2016/425 as brought into UK law and amended)

First issue: 23 March 2019 Date of Issue: 11 October 2024 Expiry*: 05 October 2027

Authorised by

C A Butcher

Certification Manager

*Subject to continued compliance and audit.

Shirley Technologies Limited, trading as BTTG®, is a UKAS accredited certification body No.5368

The attached schedule of approval forms part of this certificate.

Note: The validity of this certificate can be confirmed by contacting the Issuing Office:

BTTG®, Unit 6 Wheel Forge Way, Trafford Park, Manchester, M17 1EH, United Kingdom

Tel: +44 (0)161 876 4211 email: certification@bttg.co.uk website: www.bttg.co.uk

5368

OFC01533– v4 –22.03.2022 – Approval Level 1

Schedule of Approval
Certificate Number: 54180

First Issued:	**23 March 2019**	**Page No:**	**2 of 3**
Issue date:	**11 October 2024**	**Issued by:**	**BTTG® (Approved Body No. 0338)**
Expiry date:	**05 October 2027**	**BTTG® ref:**	**E-035477**

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

BTTG®, specified as an "approved body" under the terms of the Personal Protective Equipment Regulations (Regulation 2016/425 as brought into UK law and amended), did undertake the relevant quality assessment procedures for the manufacturing sites identified below, which were found to be in compliance with Module D "conformity to type based on quality assurance of the production process" of the Regulation, subject to any conditions in the schedule attached hereto.

This certificate authorises the use of the Mark of Conformity (the 'UKCA mark'), together with the number of the Approved Body involved in the production control phase (0338) once the manufacturer has issued a Declaration of Conformity according to Article 15 of the Regulations.

Places of Production

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

Approval Documents

BTTG/JP/Protech/08.2024

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Terms and Conditions associated with the issue of this Quality Assurance Certificate

1. This certificate is issued subject to BTTG®'s standard terms of business, available on our website.
2. Production is limited to the site(s) listed above.
3. The client must implement appropriate changes as notified by BTTG®.
4. The client must ensure the certified product is representative of the ongoing manufactured product.
5. The client must:

a) Permit ongoing surveillance and access to documentation and records, and access to the relevant equipment, location(s), area(s), personnel and clients subcontractors.

b) Investigate complaints associated with the certified products. Records of such complaints, and actions taken, must be kept by the client and made available to BTTG® when requested.

c) Allow participation of observers during surveillance audits when requested.

6. The client must only make claims consistent with the scope of certification,
7. The client must not make any misleading or unauthorised comments regarding the certified product or the certification body.
8. 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 BTTG®.
9. The client must comply with the requirements for the use of the approved body number as detailed below.
10. Changes to a client's product design, manufacturing processes, operations, location, management team or resource provision that could have an impact on the certified product shall be immediately notified to BTTG®.
11. 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.
12. This certificate remains the property of BTTG® and will be withdrawn if any of the conditions attached to its issue are not complied with.
13. The Manufacturer shall have continuous surveillance of Factory Production Control carried out by an Approved Body and a re-certification of Factory Production Control every three years.

Use of an Approved Body Number

1. The Approved Body Number must only be used:
   a) In direct association with products or systems covered by this Quality System Certificate.
   b) By holder(s) of the Certificate.
2. Use of BTTG® Approved 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 BTTG® Approved Body Number with other products or systems or schemes and with claims or information not contained in the BTTG® document.
4. The UKCA mark consists of the letters 'UKCA', in the form given in Annex II of Regulation (EC) No. 765/2008 as brought into UK law and amended, followed by BTTG®'s approved body number.

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

END OF REPORT