

B Burlington
Medical
POWERED BY STANLEY

1. PPE: X-Ray Protective Frontals: A10, F01, F17, 601, P500
X-Ray Protective Wraps: Euro, F111, F112, W113, W114, Tabard, P600
X-Ray Protective Vests and Kilts: Vest, FVest, PVest, QVest, ZVest, Kilt, K303
X-Ray Protective Collars: TSS, TSO, TSV, TSB, TSC
X-Ray Protective Small Parts including but not limited to Blockers, Caps (Cap1, Cap2);
Sleeves (SL, SL-3); Leg Wraps (LGW1, LGW2, LGW3, LGW4); Half Aprons; Gonad Shields
{GSS-OVE, GSM-OVE, GSL-OVE, GSASET-OVE, GSS-TRI, GSM-TRI, GSL-TRI, GSASET-TRI}; Mitten (LG4)
2. The manufacturer and, where applicable, authorized representatives:

Burlington Medical, LLC	ProtectX Medical Ltd.
3 Elmhurst Street	Units 1-4 Knowl Piece Bus. Ctr.
Newport News, VA 23603	Knowl Piece, Wilbury Way
	Hitchin Hertfordshire, SG4 0TY
	United Kingdom
3. This declaration of conformity is issued under the sole responsibility of the manufacturer:
Burlington Medical, LLC
3 Elmhurst Street
Newport News, VA 23603
4. The objects of this declaration for PPE are as follows:
X-Ray Protective Frontals: A10, F01, F17, 601, P500
X-Ray Protective Wraps: Euro, F111, F112, W113, W114, Tabard, P600
X-Ray Protective Vests and Kilts: Vest, FVest, PVest, QVest, ZVest, Kilt, K303
X-Ray Protective Collars: TSS, TSO, TSV, TSB, TSC
X-Ray Protective Small Parts including but not limited to Blockers, Caps (Cap1, Cap2);
Sleeves (SL, SL-3); Leg Wraps (LGW1, LGW2, LGW3, LGW4); Half Aprons; Gonad Shields
{GSS-OVE, GSM-OVE, GSL-OVE, GSASET-OVE, GSS-TRI, GSM-TRI, GSL-TRI, GSASET-TRI}; Mitten (LG4)
5. The objects of the declaration described in point 4 are in conformity with the provisions of the PPE Regulation (EU) 2016/425.
6. References are also relevant to IEC International Standard 61331-1:2014 and 61331-3:2014.
7. Reference is also relevant to EN ISO 13688:2013.
EU TYPE EXAMINATION BY: Notified Body Shirley Technologies (Europe) Limited, Sky Business Centre, Port Tunnel Business Park, Office 13 Unit 21, Clonsbaugh Business & Technology Park, Dublin 17, ROI, performed the EU-type examination in accordance with Module B (EU) 2016/425 and issued the EU-type examination certificates SH00018. These are now held by Shirley Technologies (Europe) Limited, Notified Body 2895.
UK TYPE EXAMINATION BY: Approved Body BTGT Unit 6, Wheel Forge Way, Trafford Park, Manchester, M17 1EH, UK. Performed the Module B Type examination in accordance with Module B (EU) 2016/425 as amended and brought into UK law and issued the Module B Type examination certificates 523735. These are now held by BTGT, Approved Body 0338.
8. EU SURVEILLANCE according to Module D (EU) 2016/425 was performed by Notified Body 2895, Shirley Technologies (Europe) Limited, Sky Business Centre, Port Tunnel Business Park, Office 13 Unit 21, Clonsbaugh Business & Technology Park, Dublin 17, ROI, who issued and hold Module D Certificate No. SH00993.
UK SURVEILLANCE according to Module D (EU) 2016/425 was performed by Approved Body 0338, BTGT Unit 6, Wheel Forge Way, Trafford Park, Manchester, M17 1EH, UK, who issued and hold Module D Certificate No. 54158.
9. Additional Information: The following core materials are included:
Cost Cruncher (Lead) (0.25 / 0.35 / 0.50 mm Pb Lead Equivalence);
Truelite (Lead Composite) (0.25 / 0.35 / 0.50 mm Pb Lead Equivalence);
Scatter Sentry (Lead Free) (0.25 / 0.35 / 0.50 mm Pb Lead Equivalence);
Xenolite Strata 300 Bilayer (Lead Free) (0.25 / 0.35 / 0.50 mm Pb Lead Equivalence);

Signed for and on behalf of:
Burlington Medical, LLC
3 Elmhurst Street
Newport News, VA 23603

By: Carolyn M. Small, Senior Quality Assurance Auditor

Signature _____

12 June 2023

Date _____

EU/UKCA Declaration of Conformity

Rev. 005

Updated: 16 May 2023



Shirley

Personal Protective Equipment Regulation (EU) 2016/425

Quality Assurance Certificate

Module D

Manufacturer

Burlington Medical

3 Elmhurst Street, Newport News, Virginia, VA 23603, USA

Scope:

CE marking of X-ray protective garments

Certificate Number: SH00993

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

First Issue: 11 April 2017 Date of Issue: 02 May 2023 Expiry*: 11 April 2026

Authorised by

C A Butcher
Certification Manager

*Subject to continued compliance and audit

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, Clonsillaugh Business & Technology Park, Dublin 17, ROI

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



Shirley* is a trade name of Shirley Technologies (Europe) Limited. Registered Office: Sky Business Centre, Office 13, Unit 21, Clonsillaugh Business Park, Dublin 17. A company registered in Ireland with company number 637286. VAT Number IE 557191274. The validity of all goods and services is subject to our standard terms of business, copies of which are available on request. Copyright © 2021 Shirley Technologies (Europe) Limited. All rights reserved. SH00993/STEL-V0 - 04.10.2021 - Approval Level 1



Schedule of Approval
Certificate Number: SH00993

First issued: 11 April 2017
Issue date: 02 May 2023
Expiry date: 11 April 2026

Page No: 2 of 3
Issued by: Shirley® (Notified Body No. 2895)
Shirley® ref: SH-027963

Manufacturer: Burlington Medical

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 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 'CE mark'), together with the number of the Notified Body involved in the production control phase (2895) once the manufacturer has issued a Declaration of Conformity according to Article 15 of the Regulation.

Places of Production

3 Elmhurst Street, Newport News, Virginia, VA 23603, USA

Protec Medical, Ltd., Units 1-4 Knowl Piece Bus. Ctr., Knowl Piece, Wilbury Way, Hitchin, Hertfordshire, SG4 0TY, UK

Technical Files / Models Approved

X-ray protective aprons and associated items providing protection to specific parts of the body according to EN 61331-1:2014 and EN 61331-3:2014.

Approval Documents

Report: Shirley/LE/Burlington Medical/10.2022

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Schedule of Approval
Certificate Number: SH00993

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Page No: 3 of 3
Issued by: Shirley® (Notified Body No. 2895)
Shirley® ref: SH-027963

Manufacturer: Burlington Medical

**Terms and Conditions associated with the issue of this
Quality Assurance 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 above.
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:
 - 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 Shirley® 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 Shirley®.
9. The client must comply with the requirements for the use of the notified 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 Shirley®.
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 Shirley® 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 a Notified Body and a re-certification of Factory Production Control every three years.

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 Quality System 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.
4. The EC mark consists of the letters 'CE', in the form given in Annex II of Regulation (EC) No. 765/2008, followed by Shirley®'s notified body number.

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

END OF REPORT

