BTTG

TESTING • CERTIFICATION • AUDITING

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

Certificate

Module B Type-Examination

Manufacturer

Burlington Medical, LLC

3 Elmhurst Street, Newport News, VA 23603, USA

Product Description:

X-ray protective aprons and associated items

Product Code:

See page 2 for product codes

Technical File Reference:

522609

Designated Standard(s):

EN ISO 13688:2013

Technical Specification:

EN 61331-1:2014; EN 61331-3:2014
(Modified Broad Beam Geometry, BBG*)

Certificate Number: 523735

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

First issue: 28 May 2021 Date of Issue: 28 May 2021 Expiry: 16 March 2025

Authorised by

J Lumb
Certification Officer

Authorised by

J L Wilson
Senior Certification Officer

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

BTTG® & Shirley® are trade names of Shirley Technologies Limited. Registered Office: Wira House, West Park Ring Road, Leeds, LS16 6QL. A company registered in England & Wales with company number 04669651. VAT Number GB816764800. The supply of all goods and services is subject to our standard terms of business, copies of which are available on request.
Copyright © 2021 Shirley Technologies Limited. All rights reserved
OFC01532– v2 – 17.02.2021 – Approval Level 1

Schedule of Approval
Certificate Number: 523735

First Issued:	**28 May 2021**	**Page No:**	**2 of 6**
Issue date:	**28 May 2021**	**Issued by:**	**BTTG® (Approved Body No. 0338)**
Expiry date:	**16 March 2025**	**BTTG® ref:**	**E-015574**

Manufacturer: **Burlington Medical, LLC**

Technical file ref: **522609**

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 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 Regulations 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 BTTG®, 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 protective aprons and associated items consisting of:

EN 61331-1:2014 & 61331-3:2014

Frontal Aprons	A10; F17; 601
Wrap Around Aprons	F111; VK; PVK; FVK; EURO; TABARD; QVest; ZVest
Thyroid Collars	TSS; TSO; TSV
Gonad Shields	GSS-OVE; GSM-OVE; GSL-OVE; GSASET-OVE; GSS-TRI; GSM-TRI; GSL-TRI; GSASET-TRI **(Burlite and Cost Cruncher Core Materials only)**

EN 61331-1:2014 Only

Half Apron	HALF
Sleeves	SL; SL3
Caps	Cap1; Cap2
Leg Wraps	LGW1; LGW2; LGW3; LGW4

CONTINUED ON PAGE 3

BTTG® & Shirley® are trade names of Shirley Technologies Limited. Registered Office: Wira House, West Park Ring Road, Leeds, LS16 6QL. A company registered in England & Wales with company number 04669651. VAT Number GB816764800. The supply of all goods and services is subject to our standard terms of business, copies of which are available on request.
Copyright © 2021 Shirley Technologies Limited. All rights reserved

Schedule of Approval
Certificate Number: 523735

First Issued:	**28 May 2021**	**Page No:**	**3 of 6**
Issue date:	**28 May 2021**	**Issued by:**	**BTTG™ (Notified Body No. 0338)**
Expiry date:	**16 March 2025**	**BTTG™ ref:**	**E-015574**
Manufacturer:	**Burlington Medical, LLC**		
Technical file ref:	**522609**		

Available in the following materials:

Outer/Inner Fabrics: **Nylons / Vinyls / Prints**

Protective Core Materials:

Lightweight Lead (Lead); Lead Equivalencies: 0.25 mmPb / 0.35 mmPb / 0.50 mmPb
Cost Cruncher (Lead); Lead Equivalencies: 0.25 mmPb / 0.35 mmPb / 0.50 mmPb

Burlite Mix Lead (Composite); Lead Equivalencies: 0.25 mmPb / 0.35 mmPb / 0.50 mmPb
Truelite Mix Lead (Composite); Lead Equivalencies: 0.25 mmPb / 0.35 mmPb / 0.50 mmPb

Scatter Sentry (Lead Free); Lead Free; Lead Equivalencies: 0.25 mmPb / 0.35 mmPb / 0.50 mmPb
Envirolite (Lead Free); Lead Free; Lead Equivalencies: 0.25 mmPb / 0.35 mmPb / 0.50 mmPb
Xenolite Strata 300 Bi-layer Lead Free; Lead Equivalencies: 0.25 mmPb / 0.35 mmPb / 0.50 mmPb
Kemmetech Bi-layer Lead Free; Lead Equivalencies: 0.25 mmPb / 0.35 mmP

CONTINUED ON PAGE 4

BTTG® & Shirley® are trade names of Shirley Technologies Limited. Registered Office: Wira House, West Park Ring Road, Leeds, LS16 6QL. A company registered in England & Wales with company number 04669651. VAT Number GB816764800. The supply of all goods and services is subject to our standard terms of business, copies of which are available on request.
Copyright © 2021 Shirley Technologies Limited. All rights reserved

Schedule of Approval
Certificate Number: 523735

First Issued:	**28 May 2021**	**Page No:**	**4 of 6**
Issue date:	**28 May 2021**	**Issued by:**	**BTTG® (Approved Body No. 0338)**
Expiry date:	**16 March 2025**	**BTTG® ref:**	**E-015574**
Manufacturer:	**Burlington Medical, LLC**		
Technical file ref:	**522609**		

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 with variations and adaptions based on user requirements.

The suitability of this specification was checked with respect to the Essential Health and Safety Requirements of Regulation 2016/425 as brought into UK law and amended and was found to address the requirements for this end use.

Testing of the core materials was carried out according to the Modified Broad Beam Geometry (BBG*), as detailed in the 'Recommendation for Use' PPE-R/05.34-001 approved by the European Co-ordination of Notified Bodies Vertical Groups.

Limitations of Use

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

Observations

- Not applicable.

Authorised Sub Manufacturer

ProtecX Medical Limited; 1-4 Knowl Piece Business Centre, Knowl Piece, Wilbury Way, Hitchin, Hertfordshire, SG4 0TY, UNITED KINGDOM

CONTINUED ON PAGE 5

BTTG® & Shirley® are trade names of Shirley Technologies Limited. Registered Office: Wira House, West Park Ring Road, Leeds, LS16 6QL. A company registered in England & Wales with company number 04669651. VAT Number GB816764800. The supply of all goods and services is subject to our standard terms of business, copies of which are available on request.
Copyright © 2021 Shirley Technologies Limited. All rights reserved

Schedule of Approval
Certificate Number: 523735

First Issued:	**28 May 2021**	**Page No:**	**5 of 6**
Issue date:	**28 May 2021**	**Issued by:**	**BTTG® (Approved Body No. 0338)**
Expiry date:	**16 March 2025**	**BTTG® ref:**	**E-015574**

Manufacturer: **Burlington Medical, LLC**

Technical file ref: **522609**

Approval Documents

- Lead Equivalence test report Nos. 2018110282_1; 2019050188-2; PPb 05/2019; 2019070258; 2020060011_1; 2018110282_2
- Innocuousness test report No. 44419

CONTINUED ON PAGE 6

BTTG® & Shirley® are trade names of Shirley Technologies Limited. Registered Office: Wira House, West Park Ring Road, Leeds, LS16 6QL. A company registered in England & Wales with company number 04669651. VAT Number GB816764800. The supply of all goods and services is subject to our standard terms of business, copies of which are available on request.
Copyright © 2021 Shirley Technologies Limited. All rights reserved

Schedule of Approval
Certificate Number: 523735

First Issued:	**28 May 2021**	**Page No:**	**6 of 6**
Issue date:	**28 May 2021**	**Issued by:**	**BTTG® (Approved Body No. 0338)**
Expiry date:	**16 March 2025**	**BTTG® ref:**	**E-015574**

Manufacturer: **Burlington Medical, LLC**

Technical file ref: **522609**

Terms and Conditions associated with the issue of this Type-Examination 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 in the manufacturer's Technical File, copies of which are held by the manufacturer and BTTG®, and not to any other production site(s).
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 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 BTTG® 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 BTTG®.
10. The client must comply with the requirements for the use of the approved body number as detailed below.
11. Any change to the product or quality manual / quality plan shall be immediately notified to BTTG®.
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 BTTG® and will be withdrawn if any of the conditions attached to its issue are not complied with.
13. The UK mark consists of the letters 'UKCA', in the form given in Annex II of the Regulations (EC) No 765/2008 as brought into UK law and amended, and for category III PPE, followed by the number of the approved body involved in production control monitoring (Module C2 or D).
14. This certificate does not authorise the use of the Mark of Conformity (the 'UKCA 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 Regulations is fully complied with and controlled by a written agreement with an approved body.

Use of Approved Body Number

1. The Approved 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 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.

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

END OF SCHEDULE

BTTG® & Shirley® are trade names of Shirley Technologies Limited. Registered Office: Wira House, West Park Ring Road, Leeds, LS16 6QL. A company registered in England & Wales with company number 04669651. VAT Number GB816764800. The supply of all goods and services is subject to our standard terms of business, copies of which are available on request.
Copyright © 2021 Shirley Technologies Limited. All rights reserved