Shirley

Personal Protective Equipment Regulation (EU) 2016/425

Certificate

Module B EU 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 products codes

Technical File Reference:

522609

Harmonised Standard(s):

EN ISO 13688:2013

Technical Specification:

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

Certificate Number: SH00017

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

First issue:	22 June 2021	Date of Issue:	22 June 2021	Expiry:	16 March 2025

Authorised by

S Stone

General 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

Schedule of Approval
Certificate Number: SH00017

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Issue date:	**22 June 2021**	**Issued by:**	**Shirley® (Notified Body No. 2895)**
Expiry date:	**16 March 2025**	**Shirley® ref:**	**SH-019622**

Manufacturer: **Burlington Medical, LLC**

Technical file ref: **522609**

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 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

EN 61331-1:2014 Only

Half Apron	HALF
Sleeves	SL; SL3
Caps	Cap1; Cap2
Leg Wraps	LGW1; LGW2; LGW3; LGW4
Gonad Shields	GSS-OVE; GSM-OVE; GSL-OVE; GSASET-OVE; GSS-TRI; GSM-TRI; GSL-TRI; GSASET-TRI

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Available in the following materials:

Outer/Inner Fabrics:	**Nylons / Vinyls / Prints**
Protective Core Materials:	**Regular Lead; Lead Equivalencies: 0.25 mmPb / 0.35 mmPb / 0.50 mmPb**
	Bur-Lite; Partially Leaded; Lead Equivalencies: 0.25 mmPb / 0.35 mmPb / 0.50 mmPb
	Enviro-Lite; Lead Free; Lead Equivalencies: 0.25 mmPb / 0.35 mmPb / 0.50 mmPb

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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 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 (EU) Regulation 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.

Authorised Sub Manufacturer

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

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Approval Documents

- Lead Equivalence test report Nos. 2015050150_8; 2015070344_2; 2015050150_6; 2015050150_4; 2015090276; 2016060384_2
- Innocuousness test report No. 44419

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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.

END OF SCHEDULE