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, Clonshaugh Business & Technology Park, Dublin 17, ROI

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

IVNAB PRODUCT CERTIFICATION

Schedule of Approval
Certificate Number: SH00993

First Issued:	**11 April 2017**	**Page No:**	**2 of 3**
Issue date:	**02 May 2023**	**Issued by:**	**Shirley® (Notified Body No. 2895)**
Expiry date:	**11 April 2026**	**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

Protecx 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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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