BTTG

TESTING • CERTIFICATION • AUDITING

Personal Protective Equipment Directive (89/686/EEC)

Certificate

Article 10 EC 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 schedule of approval for product codes

Technical File Reference:

522609

Harmonised Standard(s):

EN ISO 13688:2013

Technical Specification:

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

Certificate Number: 522976/1

Issued by: BTTG™ (Notified Body No. 0338 for EC Directive 89/686/EEC)

First issue: 25 June 2018 Date of Issue: 25 June 2018 Expiry: 25 June 2023

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: ppe@bttg.co.uk website: www.bttg.co.uk

Schedule of Approval
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Issue date:	**25 June 2018**	**Issued by:**	**BTTG™ (Notified Body No. 0338)**
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Manufacturer: **Burlington Medical, LLC**

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BTTG™, specified as a "notified body" under the terms of the Personal Protective Equipment Regulations 2002, did undertake the relevant type approval procedures for the equipment identified below which was found to be in compliance with the relevant provisions of EC Directive 89/686/EEC, or as amended, subject to any conditions in the schedule attached hereto. The PPE type complies with the applicable essential health and safety requirements.

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; B10; F15; F17; 201; 401; 601; 901
Wrap Around Aprons	B52; F111; VK; PVK; FVK; EURO; TABARD
Thyroid Collars	TSS; TSO; TSV
Mitten	LG4

EN 61331-1:2014 Only

Half Apron	HALF
Scoliosis Shawl	SSHAWL
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 Basic Health and Safety Requirements of EC Directive 89/686/EEC, 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, unless otherwise specified.

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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 EC Type-Examination Certificate

1. This certificate is issued subject to BTTG™'s standard terms of business.
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 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.
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 notified body number as detailed below.
10. Any change to the product or quality manual / quality plan 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. This certificate remains the property of BTTG™ and will be withdrawn if any of the conditions attached to its issue are not complied with.
12. 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 Article 11(A or B) of the Directive 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 BTTG™ 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 BTTG™ Notified Body Number with other products or systems or schemes and with claims or information not contained in the BTTG™ 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 the number of the notified body involved in production control monitoring (Article 11).

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

END OF SCHEDULE