



TESTING • CERTIFICATION • AUDITING

Personal Protective Equipment Regulation (EU) 2016/425

Certificate

Module B EU Type-Examination

Manufacturer

ProtecX Medical Limited

1-4 Knowl Piece Business Centre, Knowl Piece, Wilbury Way, Hitchin, Hertfordshire, SG4 0TY

Product Description:

X-ray protection garments with Xenolite Strata 300 Lead-free Bi-layer core material

Product Code:

Listed on following pages

Technical File Reference:

523921

Harmonised Standard(s):

EN ISO 13688:2013

Technical Specification:

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

Certificate Number: 523921/1

Issued by: BTTG™ (Notified Body No. 0338 for Regulation (EU) 2016/425)

First issue: 23 December 2020 Date of Issue: 23 December 2020 Expiry: 23 December 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: ppe@bttg.co.uk website: www.bttg.co.uk



Schedule of Approval
Certificate Number: 523921/1

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Expiry date:	23 December 2025	BTTG™ ref:	E-017017
Manufacturer:	ProtecX Medical Limited		
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BTTG™, 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 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 protection garments with Xenolite Strata 300 Lead-free Bi-layer core material consisting of:

EN 61331-1:2014 only

Open hand shield:	1202
Open finger mitt:	1203
Arm shield:	1211
Leg protectors:	1208
Lead cap:	1213

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

Apron:	1101; 1105; 1106; 1102; 1108; 1107; 1107HB; 1109; 1110; 1111; 1103; 1102FF; Pro-PK; Pro-Euro; Princess Vest Top; Pro Zip Vest Top
Thyroid collar:	1200; 1205; 2517
Dental apron:	1112

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Available in the following materials:

Outer fabric and lining:	Coated woven fabric (solid colours or patterns)
Protective core materials:	Xenolite Strata 300 Lead-free Bi-layer 0.25 mmPb Lead Equivalence Xenolite Strata 300 Lead-free Bi-layer 0.35 mmPb Lead Equivalence Xenolite Strata 300 Lead-free Bi-layer 0.50 mmPb Lead Equivalence

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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.

The suitability of this specification was checked with respect to the Essential Health and Safety Requirements of Regulation (EU) 2016/425 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 Co-ordination of Notified Bodies Vertical Groups.

Limitations of Use

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

Observations

- Not applicable.

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Approval Documents

- Material test report No. 2020060011_1
- Innocuousness information – OEKO-TEX® Test No. 14.HIN.42620

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**Terms and Conditions associated with the issue of this
EU 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. 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).
13. 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 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.

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

END OF SCHEDULE