

1. PPE: X-Ray Protective Garments and Accessories – Personal Protective Equipment against secondary ionizing radiation
2. The manufacturer and, where applicable, authorized representatives:
Burlington Medical, LLC
3 Elmhurst Street
Newport News, VA 23603
ProtecX Medical Ltd.
Units 1-4 Knowl Piece Bus. Ctr.
Knowl Piece, Wilbury Way
Hitchin Hertfordshire, SG4 0TY
United Kingdom
3. This declaration of conformity is issued under the sole responsibility of the manufacturer:
Burlington Medical, LLC
3 Elmhurst Street
Newport News, VA 23603
4. The objects of this declaration for PPE are as follows:
X-Ray Protective Frontals: A10, F01, F17, 601, P500
X-Ray Protective Wraps: Euro, F111, F112, W113, W114, Tabard, P600
X-Ray Protective Vests and Kilts: Vest, FVest, PVest, QVest, ZVest, Kilt, K303, S302
X-Ray Protective Collars: TSS, TSO, TSV, TSB, TSC
X-Ray Protective Small Parts including but not limited to Blockers, Caps (Cap1, Cap2);
Sleeves (SL, SL-3); Leg Wraps (LGW1, LGW2, LGW3, LGW4); Half Aprons; Gonad Shields
(GSS-OVE, GSM-OVE, GSL-OVE, GSASET-OVE, GSS-TRI, GSM-TRI, GSL-TRI, GSASET-TRI); Mitten (LG4)
5. The objects of the declaration described in point 4 are in conformity with the provisions of the PPE Regulation (EU) 2016/425.
6. References are also relevant to IEC International Standard 61331-1:2014 and 61331-3:2014.
7. Reference is also relevant to EN ISO 13688:2013.
EU TYPE EXAMINATION BY: Notified Body Shirley Technologies (Europe) Limited, Sky Business Centre, Port Tunnel Business Park, Office 13 Unit 21, Clonshaugh Business & Technology Park, Dublin 17, ROI, performed the EU-type examination in accordance with Module B (EU) 2016/425 and issued the EU-type examination certificate SH00018. These are now held by Shirley Technologies (Europe) Limited, Notified Body 2895.
8. **EU SURVEILLANCE** according to Module D (EU) 2016/425 was performed by Notified Body 2895, Shirley Technologies (Europe) Limited, Sky Business Centre, Port Tunnel Business Park, Office 13 Unit 21, Clonshaugh Business & Technology Park, Dublin 17, ROI, who issued and hold Module D Certificate No. SH00993.
9. Additional information: The following core materials are included:
Cost Cruncher (Lead) (0.25 / 0.35 / 0.50 mm Pb Lead Equivalence);
Truelite (Lead Composite) (0.25 / 0.35 / 0.50 mm Pb Lead Equivalence);
Xenolite Strata 500 Single Layer (Lead Free) (0.25 / 0.35 / 0.50 mm Pb Lead Equivalence)

Signed for and on behalf of:

Burlington Medical, LLC
3 Elmhurst Street
Newport News, VA 23603

By: Carolyn M. Small, Senior Quality Assurance Auditor



Signature

14 February 2026

Date

Change History				
RFC #	Date	Description	Rev.	Originator
2042	13 Feb 2026	Initial release of EU Declaration of Conformity Obsolescence of the EU/UKCA Declaration of Conformity due to the surrender of the UKCA certifications Removed the Skirt.	A	Carolyn Small – QA

Previous Change History				
RFC #	Date	Description	Rev.	Originator
1908	23 May 2024	Added Xenolite Strata 500 to the approved ATM materials for use on EU/UKCA marked products.	007	Carolyn Small – QA
	30 August 2023	Added in Skirt, S302	006	Carolyn Small – QA
	12 June 2023	Removed the B10, F15, 201, 401, 901, B52, VK, PVK, FVK, Scoliosis Shield. Added in F01, P500, W113, W114, P600, Vest, PVest, FVest, Kilt, K303, TSB, TSC, Blockers. Added in ProtecX as a subcontractor.	005	Carolyn Small – QA
	28 March 2023	Removed Lightweight Lead, Burlite Mix, Envirolite Lead Free, and Kemmetech Bi-Layer Lead Free from the document	004	Carolyn Small – QA
	09 Feb 2023	Combined all the previous separate Declarations of Conformity into one document.	003	Carolyn Small – QA
		Prior to Revision 003 there were separate Declarations of Conformity for each Attenuating Material.		