

EU/UKCA Declaration of Conformity

1. **PPE:**
 - 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
 - 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)
2. The manufacturer and, where applicable, authorized representatives:

Burlington Medical, LLC	ProtecX Medical Ltd.
3 Elmhurst Street	Units 1-4 Knowl Piece Bus. Ctr.
Newport News, VA 23603	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
 - 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 certificates SH00017 and SH00018. These are now held by Shirley Technologies (Europe) Limited, Notified Body 2895.

UK TYPE EXAMINATION BY: Approved Body BTTG Unit 6, Wheel Forge Way, Trafford Park, Manchester, M17 IEH, UK. Performed the Module B Type examination in accordance with Module B (EU) 2016/425 as amended and brought into UK law and issued the Module B Type examination certificates 523735, 523735/1, and 523723/1. These are now held by BTTG, Approved Body 0338.
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. 54158.

UK SURVEILLANCE according to Module D (EU) 2016/425 was performed by Approved Body 0338, BTTG Unit 6, Wheel Forge Way, Trafford Park, Manchester, M17 IEH, UK, who issued and hold Module D Certificate No. 54158.
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);
 - Scatter Sentry (Lead Free) (0.25 / 0.35 / 0.50 mm Pb Lead Equivalence);
 - Xenolite Strata 300 Bilayer (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 _____ Date 16 May 2023