

PROTECX MEDICAL LIMITED

EU DECLARATION OF CONFORMITY

Manufactured by: ProtecX Medical Limited, Unit 1-4 Knowl Piece Business Centre, Knowl Piece, Wilbury Way, Hitchin, Herts. SG4 0TY

We declare that the new PPE described hereafter:

Product: Xenolite Strata 300 Bi-layer Lead Free

Product name:" Xenolite Strata 300 "Lead Free X-ray protective clothing

ProtecX Medical Ltd "Bi-Layer " Lead Free X-ray protective clothing providing protection to parts of the body with a nominal lead equivalence of 0.25mmPb and 0.35mmPB and 0.50 mmPb and 1.00mmPb Mix. Range of 60kV to 110kV. This clothing is available in a range of styles referenced as:

1101-25,1102-25,1102FF-25,1103-25,1105-25,1106-25,1107-25,1107HB-25, 1108-25, 1109-25, 1110-25, 1111-25 & 1112-25, 1113-25, 1200-25, 1202-25, 1203-25, 1204-25, 1208-25, 1211-25 & 1213-25 & Pro PK-25, Pro-Euro-25, Princess Vest Top-25, Pro Zip Vest Top 25.

1101-35, 1102-35, 1102FF-35, 1103-35, 1105-35, 1106-35, 1107-35, 1107HB- 35, 1108-35, 1109-35, 1110-35, 1111-35 & 1112-35, 1113-35, 1200-35, 1202-35, 1203-35, 1204-35, 1208-35, 1211-35 & 1213-35 & Pro PK-35, Pro-Euro-35, Princess Vest Top-35, Pro Zip Vest Top 35.

1101-50, 1102-50, 1102FF-50, 1103-50, 1105-50, 1106-50, 1107-50, 1107HB- 50, 1108-50, 1109-50, 1110-50, 1111-50 & 1112-50, 1113-50, 1200-50, 1202-50, 1203-50, 1204-50, 1208-50, 1211-50 & 1213-50 & Pro PK-50, Pro-Euro-50, Princess Vest Top 50, Pro Zip Vest Top 50.

1101-MIX, 1102-MIX, 1102FF-MIX, 1103-MIX, 1105-MIX, 1106-MIX, 1107- MIX, 1107HB-MIX, 1108-MIX, 1109-MIX, 1110-MIX, 1111-MIX & 1112-MIX, 1113 MIX, 1200-MIX, 1202-MIX, 1203-MIX, 1204 MIX, 1208-MIX, 1211-MIX& 1213-MIX& Pro PK-MIX, Pro-Euro-MIX, Princess Vest Top- MIX, Pro Zip Vest Top- MIX.

1207 – 1.00mmPb.

Is in conformance with the provision of the PPE Regulations (EU) 2016/425, Manufactures technical specification: EN 61331-1:2014 BBG*, Product design is based on EN 61331-3:2014 BBG*.

Shirley® Approved Body 2895, Dublin 17, ROI, performed the EU type-examination Module B and issued the EU type examination certificate SH00827, which is held by Shirley® 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.

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. SH00627

Name of responsible person: D Gray

Place if Issue: Hitchin

Date: 05/07/2022

Signature:

Name: Duncan Gray

Position: Director

