**PROTECX MEDICAL LIMITED**

EU DECLARATION OF CONFORMITY

Signature:

Name: Duncan Gray

Position: General Manager

Name of responsible person: D Gray

Place if Issue: Hitchin

Date: 10/12/2019

We declare that the new PPE described hereafter: Product:

Product name:” Truelite “Lead Composite X-ray protective clothing.

ProtecX Medical Ltd "Burlite Mix " Lead 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:

l10l-25, 1102-25, 1102FF-25, 1103-25, 1105-25, 1106-25, 1107-25, 1107HB- 25, ll08-25, 1109-25, lll0-25, ll1l-25 & 1112-25, 1200-25, 1202-25, 1203-25, 1204-25, 1208-25, 1211-25 & 1213-25 & Pro PK-2, 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, ll08-35, 1109-35, lll0-35, ll1l-35 & 1112-35, 1113-35, 1200-35, 1202-35, 1203-35, 1204, 1208-35, 1211-35 & 1213-35 & Pro PK-35, Pro-Euro-35 - Princess Vest Top 35 – Pro Zip Vest Top 35.

l10l-50, 1102-50, 1102FF-50, 1103-50, 1105-50, 1106-50, 1107-50, 1107HB- 50, ll08-50, 1109-50, lll0-50, ll1l-50 & 1112-50,1113-50, 1200-50, 1202-50, 1203-50,1204, 1207-

& 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, 1109FF-MIX, lll0-MIX, l1ll-MIX & 1110-MIX 1200-MIX, 1202-MIX, 1203-MIX, 1204, 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\*.

Is identical to the PPE which is the subject of EU Certificate of Conformity number 523695/1 issued by BTTG. BTTG Testing & Certification Ltd, Unit 14, Wheel Forge Way, Trafford Park, Manchester Ml7 1EH, United Kingdom.

The PPEIs subject to the conformity assessment procedure set out in Module D (EU) 2016/425 Category III under the surveillance of BTTG Testing & Certification Ltd, Unit 14, Wheel Forge Way, Trafford Park, Manchester, M17 1EH, United Kingdom.

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