

# PROTECX MEDICAL LIMITED

## EC 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:

Product name: " Burlite Mix Lead "Lead 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 50kV to 150kV. 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, 1200-25, 1202-25, 1203-25, 1204-25, 1208-25, 1211-25 & 1213-25 & Pro PK-2, Pro-Euro-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, 1208-35, 1211-35 & 1213-35 & Pro PK-35, Pro-Euro-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, 1207- & Pro PK-50, Pro-Euro-50.

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

1207 – 1.00mmPb.

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

Is identical to the PPE which is the subject of EC Certificate of Conformity number 522652/1 issued by BTTG. BTTG Testing & Certification Ltd, Unit 14, Wheel Forge Way, Trafford Park, Manchester M17 1EH, United Kingdom.

Is subject to the procedures set out in Module D (Annex V111) Category III under the supervision of BTTG Testing & Certification Ltd, Unit 14, Wheel Forge Way, Trafford Park, Manchester, M17 1EH, United Kingdom.

Name of responsible person: D. Gray

Place of issue: Hitchin

Date: 19/12/2017

Signature:

Name: Duncan Gray

Position: General Manager



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