

PROTECX MEDICAL LIMITED

UKCA 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:

1101LF-25,1102LF-25,1102FFLF-25,1103LF-25,1105LF-25,1106LF-25,1107LF-25,1107HBLF- 25, 1108LF-25, 1109LF-25, 1110LF-25, 1111LF-25 & 1112LF-25,1200LF-25, 1202LF-25, 1203LF-25, 1204LF, 1208LF-25, 1211LF-25 & 1213LF-25 & Pro PKLF-25, Pro-EuroLF-25 – Princess Vest TopLF 25 – Pro Zip Vest TopLF 25

1101LF-35, 1102LF-35, 1102FFLF-35, 1103LF-35, 1105LF-35, 1106LF-35, 1107LF-35, 1107HB- 35, 1108LF-35, 1109LF-35, 1110LF-35, 1111LF-35 & 1112LF-35, 1113LF-35,1200LF-35, 1202-35, 1203-35, 1204LF, 1208LF-35, 1211LF-35 & 1213LF-35 & Pro PKLF-35, Pro-EuroLF-35 – Princess Vest TopLF 35 – Pro Zip Vest TopLF 35.

1101LF-50, 1102LF-50, 1102FFLF-50, 1103LF-50, 1105LF-50, 1106LF-50, 1107LF-50, 1107HBLF- 50, 1108LF-50, 1109LF-50, 1110LF-50, 1111LF-50 & 1112LF-50,1113LF-50, 1200LF-50, 1202LF-50, 1203LF-50, 1204LF-50, 1207LF-50, 1208LF-50, 1211LF-50 & 1213LF-50 & Pro PKLF-50, Pro-EuroLF-50 – Princess Vest TopLF 50 – Pro Zip Vest TopLF 50.

1101LF-MIX, 1102LF-MIX, 1102FFLF-MIX, 1103LF-MIX, 1105LF-MIX, 1106LF-MIX, 1107LF-MIX, 1107HBLF-MIX, 1108LF-MIX, 1109LF-MIX, 1110LF-MIX, 1111LF-MIX 1202LF-MIX, 1203LF-MIX, 1208LF-MIX, 1211LF-MIX & 1213LF-MIX & Pro PKLF-MIX, Pro-EuroLF-MIX – Princess Vest TopLF Mix – Pro Zip Vest TopLF Mix.

1207LF-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 523921/1 issued by Approved Body 0338 BTTG Testing & Certification Ltd, Unit 14, Wheel Forge Way, Trafford Park, Manchester M17 1EH, United Kingdom.

The PPE is subject to the conformity assessment procedure set out in Module D (EU) 2016/425 Category III under the surveillance of Approved Body 0338 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: 05/07/2022

Signature:

Name: Duncan Gray

Position: Director