



**PROTECH LEADED EYEWEAR INC,
DBA PROTECH MEDICAL**

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UKCA LEAD GARMENT & DRAPE DECLARATION OF CONFORMITY

This declaration of conformity is issued under the sole responsibility of Protech Leaded Eyewear, Inc. DBA Protech Medical. Declares that the Radiation Protective Garments, Aprons, Accessories & Drapes, "PPE" made from flexible, vinyl x-ray core material & described hereafter:

CORE MATERIAL

Lead (ST):
Ultralite Lead (UL):
Prolite Bilayer IEC (LFI):
Premier Bilayer IEC (BI):

LEAD EQUIVALENCE

0.125, 0.25, 0.30, 0.35, 0.375, 0.50, 0.70, 0.75, 1.00mm LE (Pb)
0.125, 0.25, 0.30, 0.35, 0.375, 0.50, 0.70, 0.75, 1.00mm LE (Pb)
0.25, 0.30, 0.35, 0.375, 0.50, 0.70, 0.75, 1.00mm LE (Pb)*
0.25, 0.35, 0.50mm LE (Pb)

KV RANGE

50 - 150 kVp
50 - 150 kVp
60 - 150 kVp
60 - 110 kVp

*Drapes and CT Shields - 0.25, 0.35, 0.375, 0.50mm Pb Lead Equivalences only

EN 61331-1:2014 AND EN 61331-3:2014

Frontal aprons (light & heavy duty)

AP-BR; AP-BA; AP-FB; AP-SD; AP-TIE; AP-VA; AP-UA; APO-FB

Front & Back aprons (light & heavy duty Closed)

AP-SKIRT; AP-SKEZ; AP-VEZ; AP-VO; AP-VFO; AP-VFW; AP-TVEST;
AP-VQ; AP-V; AP-VFBQ; AP-VFB; AP-VW; AP-WAQ; AP-WABR;
AP-WAFB; AP-MAWA; AP-MA; AP-FBM; AP-FBX; APO-FB;
AP-WAEZ; APO-WAB; AP-SKIRTQ; AP-VSL; AP-VEST; AP-VFBF;
AP-VESTQ; AP-VSFB-FO; AP-VSFO; AP-VS; APO-VSO; APO-VS

Thyroid collars (>=0.50mm LE)

AP-TCO; AP-TCS; AP-TCG; AP-TCP; AP-TCM; AP-TCB;
AP-TCV; AP-TCF; AP-TCH; APO-TCM; APO-TC

Protective Mitts (>=0.25mm LE)

AP-ANGIOMIT-R; AP-ANGIOMIT-L; AP-SLITMIT-R; AP-SLITMIT-L

Gonad/ovary shields (>=1.00mm LE)

AP-HA; AP-GONAD, AP-GS-OL

Dental aprons (>=0.35mm LE)

AP-DA; AP-DC; AP-DP; AP-DAC; APO-DA

EN 61331-1:2014 ONLY

Scatterguard Drapes (>=0.25mm le)

SG-AD; SG-ABD; SG-BD; SG-DSD; SG-EPDC-SM; SG-EPDC-LG;
SG-EPD; SG-FEM; SG-JUG; SG-MRFD; SG-NSD; SG-MPD;
SG-MPDF; SG-PPD; SG-RA; SG-SPE

Lead Accessories (>=0.25mm le)

Patient CT Shields: SH-SHLD-EYE; SG-SHLD-THY

Caps: AP-PGCAP; AP-PAGE; AP-CAP; SG-DCAP

Other: BL; ANGIO; AP-ANGIOMIT; AP-FOOT; AP-SHIN; AP-SG;
AP-SLV; AP-WINGS; AP-STOLE; AP-BG; SG-DTHY

X-Ray Protection Garments and related accessories ("PPE") described above is in conformity with the provisions of Regulation (EU) 2016/425 and Regulation (EU) 2016/425 as brought into UK Law and amended; the models satisfy the requirements of the manufacturer's technical and quality management specifications with testing based upon IEC 61331-1:2014, IEC 61331-3:2014 and applicable FDA regulations and ASTM testing standards. This is identical to the PPE which BTTG, Approved Body #0338 (6 Wheel Forge Way, Trafford Park, Stretford, Manchester M17 1EH, United Kingdom), performed the EU Module B type-examination on and issued the EU type-examination Certificate #E-038621. The PPE is subject to the conformity assessment procedure set out in Regulation (EU) 2016/425 as brought into UK Law and amended, Module D (Certificate #E-038623) under surveillance of the Approved Body BTTG, Approved Body #0338, performed at Protech Leaded Eyewear, Inc. DBA Protech Medical, 7960 Central Industrial Drive, Suite 125, West Palm Beach, Florida 33404.

Signed for and on behalf of: Protech Leaded Eyewear, Inc. DBA Protech Medical, 7960 Central Industrial Drive, Suite 125, West Palm Beach, Florida 33404.

Signature

Jarrod Parasma, President

Printed Name

March 14th, 2025

Date