



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

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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

PPE described above is in conformity with the provisions of Regulation (EU) 2016/425 and the models satisfy the requirements of the manufacturer's technical and quality management specifications with testing based upon IEC 61331-1:2014 and IEC 61331-3:2014. This is identical to the PPE which Shirley Technologies (Europe) Limited, Notified Body 2895 (Port Tunnel Business Park, Office 13 Unit 21, Dublin 17, ROI), performed the EU Module B type-examination on and issued the EU type-examination Certificate #SH00791. The PPE is subject to the conformity assessment procedure set out in Regulation (EU) 2016/425, Module D (Certificate # SH00654) under surveillance of the notified body Shirley Technologies (Europe), Limited, notified body number 2895, performed at Protech Leaded Eyewear, Inc. DBA Protech Medical, 1360 N Killian Dr. Unit 2, Lake Park, Florida 33403.

Signed for and on behalf of: Protech Leaded Eyewear, Inc. DBA Protech Medical, at 1360 N Killian Dr. Unit 2, Lake Park, FL 33403

Jarrod Parasma, President

May 20th, 2024

Signature

Printed Name

Date