



PROTECH LEADED EYEWEAR INC,
DBA PROTECH MEDICAL

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LEAD GARMENT & DRAPE DECLARATION OF CONFORMITY

Declares that the Radiation Protective Garments, Aprons, Accessories & Drapes, "PPE" made from flexible, vinyl x-ray core material & described hereafter:

CORE MATERIAL & LE

Lead (ST): 0.25, 0.35, 0.50mm LE (Pb)

Ultralight Lead (UL): 0.25, 0.35, 0.50mm LE (Pb)

Prolite Lead-Free (LFI): 0.25, 0.35, 0.50mm LE (Pb)

Bilayer (BI): 0.25, 0.35, 0.50mm LE (Pb)

LEAD EQUIVALENT CLASS

50 - 150 kVp

50 - 150 kVp

50 - 110 kVp

50 - 150 kVp

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

FRONT & BACK APRONS (LIGHT & HEAVY DUTY CLOSED)

AP-TVS; AP-VS; AP-VSFO; AP-VSFB; AP-VSFBFO; AP-WABR; AP-WAFO;
AP-WAFB; AP-MA

THYROID COLLARS ($\geq 0.50\text{MM LE}$)

AP-TCO; AP-TCS; AP-TCG; AP-TCP; AP-TCM

PROTECTIVE MITTS ($\geq 0.25\text{MM LE}$)

SLITMIT

PROTECTIVE GONAD SHIELDS ($\geq 0.50\text{MM LE}$)

AP-HA

SCROTUM/OVARY SHIELDS ($\geq 1.00\text{MM LE}$)

AP-GONAD, AP-GS-OL

DENTAL APRONS ($\geq 0.35\text{MM LE}$)

AP-DA; AP-DC; AP-DP

EN 61331-1:2014 ONLY

SCATTERGUARD DRAPES ($\geq 0.25\text{MM LE}$)

SG-MPD, SG-MPD-F, SG-PPD-F, SG-EPD-F, SG-FEAD-F, SG-PPD

PATIENT CT SHIELDS ($\geq 0.25\text{MM LE}$)

SH-SHLD-EYE, SG-SHLD-THY

LEAD ACCESSORIES ($\geq 0.25\text{MM LE}$)

Caps: AP-PGAP, AP-PAGE, AP-CAP, SG-DCAP

Other: AP-STOLE, AP-SLV, AP-SG, ANGIO

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.

This declaration of conformity is issued under the sole responsibility of the manufacturer.

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

Signature

Jarrod Parasmio, President

Printed Name

March 29th, 2022

Date