



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

1360 North Killian Drive, Unit 2  
Lake Park, FL 33403, USA

Website: protechmed.com  
Phone: 561.627.9769  
Email (USA): sales@protechmed.com  
Email (Intl.): global@protechmed.com  
Email (LatAm): LatAm@protechmed.com

## 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 & 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 (>=0.50MM LE)

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

#### PROTECTIVE MITTS (>=0.25MM LE)

SLITMIT

#### PROTECTIVE GONAD SHIELDS (>=0.50MM LE)

AP-HA

#### SCROTUM/OVARY SHIELDS (>=1.00MM LE)

AP-GONAD, AP-GS-OL

#### DENTAL APRONS (>=0.35MM LE)

AP-DA; AP-DC; AP-DP

**EN 61331-1:2014 ONLY**

#### SCATTERGUARD DRAPES (>=0.25MM LE)

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

#### PATIENT CT SHIELDS (>=0.25MM LE)

SH-SHLD-EYE, SG-SHLD-THY

#### LEAD ACCESSORIES (>=0.25MM LE)

Caps: AP-PGCAP, 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.

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 Parasmio, President

June 9th, 2023

Signature

Printed Name

Date