



PROTECH LEADED EYEWEAR INC,  
DBA PROTECH MEDICAL

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## EU DECLARATION OF CONFORMITY

DECLARES THAT THE RADIATION PROTECTIVE APRONS, ACCESSORIES & DRAPES, "PPE"  
MADE WITH FLEXIBLE 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

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### EN 61331-1:2014 & 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

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

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

Other: AP-STOLE, AP-SLV, AP-SG, ANGIO(MIT)

#### 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

are in conformity with the applicable requirements of Regulation (EU) 2016/425 and the models satisfy the requirements of the manufacturer's technical specifications based upon EN 61331-3:2014 and testing according to IEC 61331-1:2014. These radiation protective PPE garments are identical to the PPE which is the subject of EC Certificate of Conformity No 523415/1, issued by the Notified Body: BTTG and is subject to the procedure set out in Regulation (EU) 2016/425, Module C2 under the supervision of the notified body BTTG, performed at Protech Leaded Eyewear, Inc., 1360 N Killian Dr. Unit 2, Lake Park, Florida 33403.

Jarrod Parasma, President

September 24, 2020

Signature

Printed Name

Date