



**PROTECH**  
Medical

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

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

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

## EYEWEAR INSTRUCTIONS FOR USE (IFU)

### 1. INTENDED USE

Lead Glasses, Goggles, and fitovers ("Leaded Eyewear") are intended to be worn by persons who are present in the **EXAMINATION** or **OPERATING ROOM** during **MEDICAL** procedures requiring the use of x-ray/fluoroscopy. They are intended primarily to protect the eyes of the **OPERATOR from x-ray radiation**.

### 2. CAUTION

Leaded Eyewear are not rated for impact resistance and the lead lenses should not be used to protect against impact nor in any situation where possibility of an impact exists.

### 3. PROTECTION & COMPLIANCE STANDARDS: IEC 61331-1:2014 | ASTM 2547-18

**Protection Options: Lead (Pb) equivalent material (mm Pb)  $\geq$  0.50mm LE at 150kV**

**PL75:** Plano Lens 0.75mm ( $\pm$  0.05) Pb equiv.

**PL50:** Plano Lens 0.50mm ( $\pm$  0.05) Pb equiv.

**RX75:** Prescription lens 0.75mm ( $\pm$  0.05) Pb equiv.

**RX50:** Prescription lens 0.50mm ( $\pm$  0.05) Pb equiv.

**SS:** Lead strip side shield 0.50mm ( $\pm$  0.05) Pb equiv.

**SS50:** Lead lens side shield 0.50mm ( $\pm$  0.05) Pb equiv.

**SS75:** Lead lens side shield 0.75mm ( $\pm$  0.05) Pb equiv.

### 4. GENERAL INSTRUCTIONS

#### PACKAGING & STORAGE

Leaded Eyewear should be stored in a protective case in normal room temperature and low humidity conditions when not in use.

#### CLEANING & DISINFECTING

**a. Lenses:** Never use ammonia or chlorine-based cleaners. Use of alcohol is permitted for lenses that do not possess an anti-reflective (A/R) coat. To clean A/R coat lenses soak in diluted soap and water. DO NOT allow water to remain or dry onto the lenses as this can discolor/damage the lens. Wipe and dry using a Protech cleaning cloth or equivalent soft, lint free cloth.

**b. Frame:** Use any standard eyewear cleaning cloth. Diluted soap and water usually will not discolor or damage the frame.

#### MAINTENANCE & REPLACEMENT

**a. Maintenance:** Examine Leaded Eyewear frequently and before each use. Cease use and replace or repair immediately if the eyewear are chipped, pitted, or damaged. You may tighten screws/hinges if they loosen.

**b. Replacement:** Use only CE or Protech approved lenses and frames to repair the eyewear or request an RMA (return/repair) through your local representative.

### 5. EU TYPE

PPE is in conformity with the provisions of Regulation (EU) 2016/425 and the models satisfy the requirements of the manufacturer's technical specifications, testing based upon IEC 61331- 1:2014 and internal quality management procedures. This is identical to the PPE which is the subject of EU **Module B Type-Examination Certificate 523548/1 issued by BTTG Notified Body 0338**, Manchester M17 1EH whom performed the EU type-examination (Module B), which is now held by **Shirley, Notified Body 2895**, Port Tunnel Business Park, Office 13 Unit 21, Dublin 17, ROI and is subject to the procedure set out in Regulation (EU) 2016/425, Module D under the supervision of the notified body Shirley Technologies (Europe) Limited (Sky Business Centre, Port Tunnel Business Park, Office 13 Unit 21, Dublin 17, ROI), performed at Protech Leaded Eyewear, Inc., 1360 N Killian Dr. Unit 2, Lake Park, Florida 33403.

### 6. WARRANTY POLICY

Protech's Leaded Eyewear are warranted to be free of defects in materials and workmanship to the original purchaser for **one year**. If a defect appears, a return request must be made with Protech or authorized reseller. Protech will issue an RMA form to be completed and submitted along with the return of merchandise. All returns must be accompanied by an RMA with valid RMA #. All returns will be evaluated and examined.

Protech will either repair or replace the defective item or part without charge to the purchaser. This warranty is void when the product has been tampered with, when repairs or attempted repairs have been made by unauthorized persons, or when the item has been subject to misuse, abuse or damage in transit.