PROTECH LEADED EYEWEAR INC,
DBA PROTECH MEDICAL

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LEAD GARMENTS & ACCESSORIES INSTRUCTIONS FOR USE (IFU)

1. INTENDED USE

Lead Garments are worn by healthcare professionals to protect them from the harmful effects of x-ray radiation during medical & other procedures requiring the use of x-ray/fluoroscopy. Lead garments are usually worn in combination with other products to provide complete protection from x-ray. You must ensure that your lead garment fits correctly and is properly worn for effective protection.

2. CAUTION

Always check to ensure your lead garment is in good, working condition and has not been scratched or punctured. Pin holes or other damage to the protective core material can compromise protection and use of Lead Garment should cease immediately until it has been properly repaired or replaced.

3. PROTECTION & COMPLIANCE STANDARDS

EN 61331-1:2014: (EU) Protective devices against Diagnostic Medical X-ray radiation. (Determination of attenuation properties of material)
EN 61331-3:2014: (EU) Protective devices against diagnostic medical X-radiation Part 3: Protective clothing, Eyewear and Protective Patient shields.
ASTM 2547-18: (USA) Standard test method for determining the attenuation properties in a primary x-ray beam of materials used against radiation.

4. GENERAL INFORMATION

Upon receipt, please inspect Lead Garment for damages (holes, cuts, tears, rips, undone seams). Protech uses crush proof boxes when shipping its Lead Garments, but accidents do happen! Sizing and other Lead Garment information may vary based upon customization or special requests. For additional product details, please refer to the lead garment's sewn-on label or other included documentation.

PACKAGING & STORAGE

Keep Lead Garment out of direct sunlight and prolonged exposure to extreme heat. You may roll Lead Garment and transport in a Protech duffle bag or box, but never sharply fold or crease your Lead Garment. Always store Lead Garment on appropriate metal hanger or lay flat on the ground or a countertop if hanger is not available.

MAINTENANCE & REPAIRS

a. Maintenance: It is important to establish a consistent, deep-cleaning schedule to mitigate the risk of pathogen transmission. Lead garments should be wiped clean after each use. Lead Garment fabrics can be cleaned by using mild soap diluted with room temperature water. Clorox hydrogen peroxide in diluted form is permissible. **PDI Sani-Cloth® AF3 Germicidal Disposable Wipes as well as CaviCide® wipes are approved for use on Protech aprons.** Do not use petroleum-based cleaning solvents or solutions containing bleach. Do not machine wash or dry. **NOTE:** Protech's lead garment inspection software can help record results of annual PPE (garment) inspections. May not be available in all areas or countries.
b. Repairs: For repairs, alterations, trade-ins, recovery and other services, please contact Protech or your local representative.

DISPOSAL

Users must dispose of Lead Garments and accessories by complying with local, state, and federal or international regulations where applicable.

5. EU TYPE EXAMINATION

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.

6. WARRANTY POLICY

Protech's **Lead Garments** are warranted to be free of defects in materials and workmanship to the original purchaser for **two years.** 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.