

EU TYPE-EXAMINATION CERTIFICATE

Regulation (EU) 2016/425, MODULE B

0598/PPE/22/3897 Issue 1

Product X-ray Protective Clothing

Model Lightweight Lead Vinyl (LLV)

Trademark rego

Certificate Holder / Manufacturer REGO X-RAY GmbH
Stuttgarter Strasse 5, 86154, Augsburg, Bavaria, Germany

Product complies with the applicable essential health and safety requirements of Regulation (EU) 2016/425 and standard(s) mentioned below

Standard(s)

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Other Information

Manufacturer's technical specification (based on IEC 61331-3:2014 (Protective devices against diagnostic medical X-radiation – Part 3: Protective clothing and protective devices for gonads.) and on testing to IEC 61331-1:2014 broad beam method as per rfu sheet PPE-R/05.34-001)

This certificate shall be used in conjunction with conformity assessment procedure module C2 or D.

Validity

This certificate is valid until 2027-09-28.

Date of issue

2022-09-28

SGS Fimko Ltd

Signature



Kelvin Shepherd

SGS Fimko Ltd is a Notified Body (0598) according to the Personal Protective Equipment Regulation (EU)



Additional information X-ray protective clothing using a Lightweight Lead Vinyl attenuation material, providing protection to parts of the body with various nominal lead equivalences as detailed below. This clothing is available in a range of styles each in various sizes & various cosmetic finishes.

Nominal Lead Equivalences @ 50-150 kV	Style
0.25 mm Pb for both the front and back. 0.35 mm Pb for the front and 0.25 mm Pb for the back. 0.50 mm Pb for the front and 0.25 mm Pb for the back.	Coat Apron C+ with Velcro closure, Coat Apron C+ with Belt, Double-sided Apron, wrap around apron, wrap around apron fully overlapping. Skirt & Vest (set, which must be worn together as an ensemble). Vest & Skirt Wrap Model (set, which must be worn together as an ensemble).
0.50 mm Pb for the front and 0.25 mm Pb for the back.	Coat apron for children, Wrap around apron for children
0.25mm Pb	Surgical Aprons.
0.35 mm Pb for the front 0.50 mm Pb for the front	Dental Aprons, Surgical Aprons
0.50 mm Pb	Half Apron with belt with Velcro closure Standard Thyroid Collar, Sternum Thyroid Collar, Panoramic Thyroid Collar, Protection Cap Shin Protection, Breast Protection
1.0 mm Pb	Ovary Shields, Ovary shields for children Gonad Shields, Gonad shields for children

All of the garments must be worn following the manufacturer's instructions for use to obtain the claimed level of protection.

Contract No: GB-CERT220700375

The full details of the assessment are given in Technical file: TFR-0002, dated 20/06/2022