

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 / REGO X-RAY GmbH

Manufacturer Stuttgarter Strasse 5, 86154, Augsberg, Bavaria, Germany

Product complies with the applicable essential health and safety requirements of

Regulation (EU) 2016/425 and standard(s) mentioned below

Standard(s)

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.

2022-09-28 Date of issue

SGS Fimko Ltd

Signature

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Kelvin Shepherd

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

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Business ID 0978538-5

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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	Style
@ 50-150 kV	188580.458585858 6895855585858 68959538585555
0.25 mm Pb for both the front	Coat Apron C+ with Velcro closure,
and back.	Coat Apron C+ with Belt, Double-sided
0.35 mm Pb for the front and	Apron, wrap around apron, wrap
0.25 mm Pb for the back.	around apron fully overlapping.
0.50 mm Pb for the front and	Skirt & Vest (set, which must be worn
0.25 mm Pb for the back.	together as an ensemble). Vest & Skirt
398438555685685685685568556856856856856856856	Wrap Model (set, which must be worn
C3G365G5C5G5C5G5C5G5C5G5C5G5C5G5C5G5C5G5C5G5	together as an ensemble).
0.50 mm Pb for the front and	Coat apron for children, Wrap around
0.25 mm Pb for the back.	apron for children
0.25mm Pb	Surgical Aprons.
0.35 mm Pb for the front	Dental Aprons, Surgical Aprons
0.50 mm Pb for the front	65565656565656 65565656565656 6556565656565656
0.50 mm Pb	Half Apron with belt with Velcro closure
76363636565 65656565656565656565656565656	Standard Thyroid Collar, Sternum
**************************************	Thyroid Collar, Panoramic Thyroid
5686368685686868686868686868686868686868	Collar, Protection Cap
GSGSGSGSGSGSGSGSGSGSGSGSGSGSGSGSGSGSGS	Shin Protection, Breast Protection
1.0 mm Pb	Ovary Shields, Ovary shields for
GSGSGBGSGSGSGSGSGSGSGSGSGSGSGSGSGSGSGSG	children
56565656565656565656565656565656565656	Gonad Shields, Gonad shields for
658565656565858585656565656565656565656	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



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