



Personal Protective Equipment Regulation (EU) 2016/425

Certificate

Module B EU Type-Examination

Manufacturer

Imaging Solutions Pty Ltd

30-36 Relentless Court, Park Ridge, QLD, 4125, Australia

Product Description:

X-ray Aprons and Accessories

Product Code:

See pages 2-3 for product codes

Technical File Reference:

523556

Harmonised Standard(s):

EN ISO 13688:2013/A1:2021

Technical Specification:

EN 61331-1:2014; EN 61331-3:2014
(Modified Broad Beam Geometry, BBG*)

Certificate Number: SH00127

Issued by: Shirley® (Notified Body No. 2895 for Regulation (EU) 2016/425)

First issue: 05 November 2021 **Date of Issue:** 01 October 2025 **Expiry:** 19 November 2029

Authorised by

J Lumb

Senior Certification Officer

The attached schedule of approval forms part of this certificate.

Note: The validity of this certificate can be confirmed by contacting the Issuing Office:
Shirley Technologies (Europe) Limited, Sky Business Centre, Port Tunnel Business Park, Office 13
Unit 21, Clonsaugh Business & Technology Park, Dublin 17, ROI

Tel: +353 (0) 01894 1448 **email:** info@shirley.ie **website:** www.shirley.ie



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Shirley®, specified as a "notified body" under the terms of the Regulation (EU) 2016/425 of the European Parliament and of the Council on personal protective equipment, did undertake the relevant type approval procedures for the equipment identified below which was found to be in compliance with the relevant provisions of Annex V (Module B) of the Regulation and with the applicable essential health and safety requirements, subject to any conditions in the schedule attached hereto.

The certificate relates specifically to the PPE items described and depicted in the manufacturer's Technical File, copies of which are held by the manufacturer and Shirley®, and not to any other items.

The certificate remains valid unless cancelled or revoked, provided the conditions in the attached schedule are complied with and the equipment remains satisfactory in service.

Description of product

X-ray Aprons and Accessories consisting of:

EN 61331-1:2014 and EN 61331-3:2014

One-piece open aprons	RAD-AP-FB; RAD-AP-BR; RAD-AP-VC; RAD-AP-BA; RAD-AP-TA; RAD-AP-SD; RAD-AP-UA RAD-AP-FB-EP*; RAD-AP-FB-ES* (* = suffix configuration code) RAD-PP-AP-FB-LC; RAD-PP-AP-FB-MC; RAD-PP-AP-FB-SC
One-piece closed aprons	RAD-AP-WA-BR; RAD-AP-WA-BR-FO; RAD-AP-WA; RAD-AP-WA-FO; RAD-AP-SM; RAD-AP-MA RAD-AP-WA-BR-EP*; RAD-AP-WA-BR-ES* (* = suffix configuration code) RAD-PP-AP-WA-LC; RAD-PP-AP-WA-MC; RAD-PP-AP-WA-SC
Two-piece closed aprons	RAD-AP-VS-BR; RAD-AP-VS-BR-FO; RAD-AP-VS; RAD-AP-VS-FO; RAD-AP-VS-RV; RAD-AP-VS-FB; RAD-AP-VE-BR; RAD-AP-VE-BR-FO; RAD-AP-VE; RAD-AP-VE-FO; RAD-AP-VE-RV; RAD-AP-VE-FB-VC; RAD-AP-SK RAD-AP-VS-BR-EP*; RAD-AP-VS-BR-ES* (* = suffix configuration code)

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Thyroid Collars	RAD-AC-TC-CT; RAD-AC-TC-ST; RAD-AC-TC-VS; RAD-AC-TC-VF RAD-AC-TC-CT-EP*; RAD-AC-TC-CT-ES* (* = suffix configuration code)
Gonad Aprons	RAD-PP-AP-GA-LA; RAD-PP-AP-GA-MA; RAD-PP-AP-GA-SC; RAD-PP-AP-GA-XC; RAD-PP-AP-GA-SET
Gonad Shields	RAD-PP-SO-SET
Dental Aprons	RAD-PP-AP-DA-LA; RAD-PP-AP-DA-SC; RAD-PP-AP-DA-SET; RAD-PP-AP-PA-LA; RAD-PP-AP-PA-SC; RAD-PP-AP-PA-SET

EN 61331-1:2014 only

Accessories	RAD-AC-CP; RAD-AC-DP; RAD-AC-AG; RAD-AC-AS; RAD-AC-SG;
Half Aprons	RAD-PP-AP-HA-LA; RAD-PP-AP-HA-MA; RAD-PP-AP-HA-SC; RAD-PP-AP-HA-SET
Breast Shields	RAD-PP-BT-LA; RAD-PP-BT-MA; RAD-PP-BT-SET; RAD-PP-BS-LA; RAD-PP-BS-MA; RAD-PP-BS-SET
Patient Drapes:	RAD-PP-GS-L; RAD-PP-GS-M; RAD-PP-GS-S (for protection to patient from direct radiation)

Available in the following materials:

Protective Core Materials:

RADcore Optima Bi-Layer Non-Lead 60-110kV:

Ws ≥ 2.80 kg/m² with Lead Equivalence of 0.25 mmPb for 60-110 kV

Ws ≥ 3.90 kg/m² with Lead Equivalence of 0.35 mmPb for 60-110 kV

Ws ≥ 5.68 kg/m² with Lead Equivalence of 0.50 mmPb for 60-110 kV

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RADcore Optima Bi-Layer Non-Lead 50-150 kV:

Ws \geq 2.97 kg/m² with Lead Equivalence of 0.25 mmPb for 50-150 kV
Ws \geq 4.13 kg/m² with Lead Equivalence of 0.35 mmPb for 50-150 kV
Ws \geq 5.90 kg/m² with Lead Equivalence of 0.50 mmPb for 50-150 kV

RADcore Optima AL-Layer Non-Lead:

Ws \geq 3.07 kg/m² with Lead Equivalence of 0.25 mmPb for 50-150 kV
Ws \geq 6.15 kg/m² with Lead Equivalence of 0.50 mmPb for 50-150 kV

RADcore Optima Bi-Layer Low-Lead:

Ws \geq 2.90 kg/m² with Lead Equivalence of 0.25 mmPb for 60-110 kV
Ws \geq 3.99 kg/m² with Lead Equivalence of 0.35 mmPb for 60-110 kV
Ws \geq 5.80 kg/m² with Lead Equivalence of 0.50 mmPb for 60-110 kV

RADcore Optima Bi-Layer + Low-Lead:

Ws \geq 3.11 kg/m² with Lead Equivalence of 0.25 mmPb for 50-150 kV
Ws \geq 4.38 kg/m² with Lead Equivalence of 0.35 mmPb for 50-150 kV
Ws \geq 6.72 kg/m² with Lead Equivalence of 0.50 mmPb for 50-150 kV

RADcore Assure Non-Lead:

Ws \geq 1.70 kg/m² with Lead Equivalence of 0.125 mmPb for 50-150 kV
Ws \geq 2.38 kg/m² with Lead Equivalence of 0.175 mmPb for 50-150 kV
Ws \geq 3.42 kg/m² with Lead Equivalence of 0.25 mmPb for 50-150 kV
Ws \geq 4.79 kg/m² with Lead Equivalence of 0.35 mmPb for 50-150 kV
Ws \geq 6.84 kg/m² with Lead Equivalence of 0.50 mmPb for 50-150 kV
Ws \geq 9.63 kg/m² with Lead Equivalence of 0.70 mmPb for 60-150 kV
Ws \geq 10.25 kg/m² with Lead Equivalence of 0.75 mmPb for 60-150 kV
Ws \geq 13.70 kg/m² with Lead Equivalence of 1.00 mmPb for 60-150 kV

RADcore Original Non-Lead:

Ws \geq 3.13 kg/m² with Lead Equivalence of 0.25 mmPb for 60-110 kV
Ws \geq 4.39 kg/m² with Lead Equivalence of 0.35 mmPb for 60-110 kV
Ws \geq 6.35 kg/m² with Lead Equivalence of 0.50 mmPb for 60-110 kV

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RADcore Balance Non-Lead:

Ws \geq 2.84 kg/m² with Lead Equivalence of 0.25 mmPb for 60-120 kV
Ws \geq 4.29 kg/m² with Lead Equivalence of 0.35 mmPb for 60-150 kV
Ws \geq 5.69 kg/m² with Lead Equivalence of 0.50 mmPb for 60-120 kV

RADcore Essential Lead:

Ws \geq 4.59 kg/m² with Lead Equivalence of 0.25 mmPb for 50-150 kV
Ws \geq 6.10 kg/m² with Lead Equivalence of 0.35 mmPb for 50-150 kV
Ws \geq 7.68 kg/m² with Lead Equivalence of 0.50 mmPb for 50-150 kV
Ws \geq 13.95 kg/m² with Lead Equivalence of 1.00 mmPb for 70-150 kV

RADcore Essential Low-Lead:

Ws \geq 4.38 kg/m² with Lead Equivalence of 0.25 mmPb for 50-150 kV
Ws \geq 5.76 kg/m² with Lead Equivalence of 0.35 mmPb for 50-150 kV
Ws \geq 7.27 kg/m² with Lead Equivalence of 0.50 mmPb for 60-150 kV
Ws \geq 13.19 kg/m² with Lead Equivalence of 1.00 mmPb for 70-150 kV

RADcore Essential Non-Lead:

Ws \geq 4.15 kg/m² with Lead Equivalence of 0.25 mmPb for 50-150 kV
Ws \geq 5.63 kg/m² with Lead Equivalence of 0.35 mmPb for 50-150 kV
Ws \geq 7.01 kg/m² with Lead Equivalence of 0.50 mmPb for 60-150 kV
Ws \geq 12.63 kg/m² with Lead Equivalence of 1.00 mmPb for 70-150 kV

Outer Material: Nylon; 100%; 300-400 Denier +/- 10%
Polyester; 100%; 300 Denier +/- 10%
Nylon/Polyester; 70/30% +/- 10%; 300-400 Denier +/- 10%
Polyurethane/Polyamide ; 60/40% +/- 10%; 230gsm +/- 10%
Polyvinyl Chloride/Polyester; 70/30% +/- 10%; 250gsm +/- 10%

Lining Material: Nylon; 100%; 200 Denier +/- 10%
Nylon; 100%; 110-115 gsm +/- 10%
Polyester/Spandex; 84/16%, 200 gsm +/- 10%

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Manufacturers Technical Specification

The manufacturer's Technical Specification for the end use of X-Ray Protective Clothing and accessories was based on testing according to EN 61331-1:2014. Product design is based on EN 61331-3:2014.

The suitability of this specification was checked with respect to the Essential Health and Safety Requirements of Regulation (EU) 2016/425, and was found to address the requirements for this end use.

Testing of the core materials was carried out according to the Modified Broad Beam Geometry (BBG*), as detailed in the 'Recommendation for Use' PPE-R/05.34-001 approved by the Co-ordination of Notified Bodies Vertical Group 5.

Limitations of Use

- Usage, maintenance and storage as per manufacturer's instructions.

Observations

- Not Applicable.

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Approval Documents

- Material test report Nos. PPb 29/2024; 2018110282_2; P-0040-19; P-0041-19; P-0042-19; 201807339_2; 2023070325_9; 2023070325_8; 2023070325_13; 2023070113-IR-D; 2023070113-IR-A
- Innocuousness test report Nos. E-010610; 23.04135.01; E-034459; E-034460; E-034461; E-034462; E-034463; E-034464; E-034465; E-034466
- Ergonomic test report Nos. E-008107/A; E-008107/B; E-008107/C

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Terms and Conditions associated with the issue of this EU Type-Examination Certificate

1. This certificate is issued subject to Shirley®'s standard terms of business, available from our website.
2. Production is limited to the site(s) listed in the manufacturer's Technical File, copies of which are held by the manufacturer and Shirley®, and not to any other production site(s).
3. The client must implement appropriate changes as notified by Shirley®.
4. The client must ensure the certified product is representative of the ongoing manufactured product.
5. The client must make provision for access to relevant documents and records.
6. The client must investigate complaints associated with the certified products. Records of such complaints, and actions taken, must be kept by the client and made available to Shirley® when requested.
7. The client must only make claims consistent with the scope of certification,
8. The client must not make any misleading or unauthorised comments regarding the certified product or the certification body.
9. The client must upon suspension, withdrawal, or termination of certification discontinue the use of all advertising matter that contains any reference thereto and take action to return this certificate to Shirley®.
10. The client must comply with the requirements for the use of the notified body number as detailed below.
11. Any change to the product or quality manual / quality plan shall be immediately notified to Shirley®.
12. This certificate is issued in the English language only. It is the responsibility of the Manufacturer / Authorised Representative to obtain and supply language versions acceptable to the country where the product is to be sold. This certificate remains the property of Shirley® and will be withdrawn if any of the conditions attached to its issue are not complied with.
13. The EC mark consists of the letters 'CE', in the form given in Annex II of Regulation (EC) No 765/2008 and for category III PPE, followed by the number of the notified body involved in production control monitoring (Module C2 or D).
14. This certificate does not authorise the use of the Mark of Conformity (the 'CE mark'), which may only be affixed to the above type approved equipment and a Manufacturer's Declaration of Conformity issued when Module C2 or D of the Regulation is fully complied with and controlled by a written agreement with a notified body.

Use of Notified Body Number

1. The Notified Body Number must only be used
 - a. In direct association with products or systems covered by this Type-Examination Certificate.
 - b. by holder(s) of the Certificate.
2. Use of Shirley® Notified Body Number does not extend to other companies which are:
 - a. part of the same corporate group as the Certificate holding company: or
 - b. named in a Certificate, for example as a supplier.
3. Particular care must always be taken to avoid the association of the Shirley® Notified Body Number with other products or systems or schemes and with claims or information not contained in the Shirley® document.

If any of the above requirements are not met Shirley® will seek to suspend, withdraw or terminate this certificate.

END OF SCHEDULE