

UKCA Type Examination Certificate

This is to certify that:

Infab, LLC
1040 Avenida Acaso
Camarillo
California
93012-8712
USA

Holds Certificate Number:

UKCA 820497

In respect of:

**Radiation Protective Clothing to meet
Annex II of the PPE Regulation
2016/425, as amended to apply in GB**

On the basis that BSI carried out the relevant Type Examination procedures under the requirements with the Regulation 2016/425 on Personal Protective Equipment, as amended to apply in GB (PPE) Annex V (Module B) and meets the relevant health and safety requirements specified in Annex II.

For and on behalf of BSI, an Approved
Body for the above Regulation
(Approved Body Number 0086):

Shahm Barhom, Group Product Certification Director

First Issued: 2025-02-26

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Range: X-Ray Protective Clothing

Models:

Product Type	Product Codes
Aprons, Vest, and Skirts	103, 203, 303, 403, 503, 603, 703, 803, 903, 103S, B103, B203, B303, B403, B503, B603, B703, B803, B903, BL103, L103, AWC, DTL-TECH, DTL-CHILD, DTL-CHILD-TC, DTL-PANO, DPR, EBA, EVAS, EVST, FCW, HSV, LSF, LSW, MAT-FW, MAT-S1, MWA, RVAS, RVST, SDA, SDO, SKT, SPL, SSA, TFAM, UFW, UVS, UFP, VAS, WBT, 683401, 683402, 683403, 683404
Thyroid Collars	MTC, SVT, REV-TC, NST, TCV, TC, 300102, DTCC, REV-SLV-1
Limb Protection	455001, 444000, 444005, 444010
Patient Protection	DPR, GND, PGS, 684120
Thinking Caps	399991, 399992, 399993, 399994, 399998, 399999, 400000, 400001, 400002, 400003, 400007, 400008, 400009, 400010, 400011, 400012, 400020, 400021, 400022, 400023, 400025, 400026, 400027, 400030, 400031, 400032, 400033, 400034
Scatter Armor	SA-AGS, SA-BSS, SA-DDD, SA-EPS, SA-MPF, SA-MPS, SA-PER
Lead Gloves	683300, 683303, 683308, 683309, 683700, 683701, 683702, 683710, 683711, 683712, 684000

Products are available in the following protective materials:

Lead-free material	0.25 / 0.35 / 0.50 mm Pb
Lightweight Lead Material	0.25 / 0.50 mm Pb

Classification: Protective clothing for X-Ray protection

Description: The above table lists garments and styles of x-ray radiation protection aprons and related accessories. This list is non-exhaustive and does not describe every product code. Additional items may be covered that are variants within the range of products listed above and compliant to the requirements of EN 61331-3:2014. The products are designed to protect the wearer or technician against ionizing radiation in the radiologic tube voltage range of 60 - 110 kV. Garments do not provide chemical protection.

Construction: The Infab fabric-based radiation protection shields are made from two layers of fabric and a layer(s) of radiation-attenuating material. The fabric is available in nylon or polyester. The radiation-attenuating material is available in lead-based material or lead-free material. The lead-based material is made of lead-oxide encapsulated in a vinyl resin. The lead-free radiation attenuating material is made of heavy metal composites encapsulated in vinyl resin.

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Protective areas: Protective Aprons offer protection to the front of the body from the throat to at least the knees, the entire breastbone, and the shoulders. Closed Protective Aprons additionally protect sides of the body and back down to the knees.

Vest and Skirt two-piece design, provides the protection of an apron when used as an integrated system.

Protective Aprons for Dental Use are designed to protect front of the body from the throat to at least below the gonads, the entire breastbone, and shoulders.

Thyroid collars/shields protect front half of the neck, including the thyroid gland and extend below jaw line.

Limb protection provides protection from wrist to elbow or below knee to ankle.

Patient Protection garments offer protection of gonads and ovaries.

Thinking Caps protects the top and sides of the head from scatter radiation.

Scatter Armor protects patient from scatter radiation during medical procedures.

Lead Gloves protect hand, wrist and lower forearm.

Products are reusable and available in multiple colors and patterns.

Category:

Category III - complex

Size Range:

Garment sizes range from xSmall to 5x Large, including custom sizes, available for most products.

Technical Specification:

Type Examination for PPE product listed in this certificate meeting Essential Health and Safety Requirements of the Annex II of the PPE Regulation 2016/425 as amended to apply in GB, utilising aspects of the following standards:

EN IEC 61331-3:2014	Protective devices against diagnostic medical X-radiation – Protective clothing, eyewear and protective patient shields.
EN IEC 61331-1:2014	Protective devices against diagnostic medical X-radiation – Determination of attenuation properties of materials.
EN ISO 13688:2013+A1:2021	Protective Clothing. General Requirements.

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Performance:

General requirements to BS EN ISO 13688:2013+A1:2021

Characteristic	Result
pH	PASS
Azo Dyes	PASS

Attenuation Properties to EN IEC 61331-1:2014 (modified Broad Beam Geometry method *mBBG)

0.25mm Bi-Layer Lead-Free Material

kV	Attenuation Ratio	LEV mm Pb
60	35.5	0.2347
70	21.4	0.2433
90	10.5	0.2541
110	6.95	0.2441

0.35mm Bi-Layer Lead-Free Material

kV	Attenuation Ratio	LEV mm Pb
60	115	0.3600 PASS
70	50.8	0.3589 PASS
90	18.3	0.3617 PASS
110	11.1	0.3412 PASS

0.5mm Bi-Layer Lead-Free Material

kV	Attenuation Ratio	LEV mm Pb
60	560	0.5627
70	225	0.6036
90	57	0.6360
110	28.1	0.5698

0.25mm Lead-Free Material (Bismuth)

kV	Attenuation Ratio	LEV mm Pb
60	83.0	0.3228
70	38.3	0.3190
90	15.1	0.3226
110	9.94	0.3169

0.25 Lightweight Lead Material

kV	Attenuation Ratio	LEV mm Pb
60	42.2	0.2518
70	23.6	0.2556
90	11	0.2616
110	7.64	0.2627

0.5 Lightweight Lead Material

kV	Attenuation Ratio	LEV mm Pb
60	356	0.5007
70	125	0.4994
90	34.1	0.5026
110	21.7	0.5015

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Certificate Administration Details

Technical File Reference: TF-24-A_PPE TECHNICAL FILE_2024 0529

Certificate Amendment Record:

Issue Date	Comments
February 2025	First issue

Internal BSI Project Number

0086:25:30316975

Certificate validity:

The Certificate holder is responsible for ensuring that the Approved Body is advised of changes to any aspect of the overall process utilised in the manufacture of the product, failure to do so could invalidate the Certificate in respect of product manufactured following the introduction of such changes.

Monitoring of manufactured PPE

The validity of the Certificate for the products is also dependent on the maintenance of the Conformity to Type Based on Quality Assurance of the Production Process, Annex VIII (Module D), as referenced on BSI issued Certificate UKCA 820498.

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