EU Type Examination Certificate

This is to certify that:

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

Holds Certificate Number: CE 805104

In respect of:

Radiation Protective Clothing, Eyewear and Related Accessories to meet the requirements of Annex II of the Regulation (EU) 2016/425

on the basis that BSI carried out the relevant Type Examination procedures under the requirements with the Regulation (EU) 2016/425 of the European Parliament and Council relating to Personal Protective Equipment Regulation (PPE) Annex V (Module B) and meets the relevant health and safety requirements specified in Annex II

For and on behalf of BSI, a Notified Body for the above Regulation (Notified Body Number 2797):

Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

First Issued: 2025-02-25
Latest Issue: 2026-11-04

Effective Date: 2026-11-04
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PRODUCTS
RvA C 646

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To check its validity telephone +31 20 3460780. An electronic certificate can be authenticated online.

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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, 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
70	50.8	0.3589
90	18.3	0.3617
110	11.1	0.3412

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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Range: **Radiation Protective Eyewear**

Models: Achilles, Cyber Flex, EVO, Fitovers, Gucci, Incredibles, Maxx, Nike, Oakley, Premium Wraps, RayBan, Zion, and Zone.

Available in the following materials- 0.75 mm Pb L.E

Product Codes	Measurement/Dimension Specification
LL-BC4	Base Curve 4/80mm x2.8mm)
LL-BC6	Base Curve 6/80mm x2.8mm)
LL-BC8	Base Curve 8/80mm x2.8mm)

Classification: Protective Eyewear

Description: The above table lists materials/lens used for the protective eyewear. INFAB radiation-attenuating eyewear is Personal Protective Equipment (PPE Category III) intended

to reduce occupational exposure of the wearer's eyes to ionizing scatter radiation in environments where X-ray or fluoroscopic imaging systems are in use. The eyewear is designed for personnel who work in the vicinity of medical imaging equipment and is intended to be worn as part of a radiation-protection ensemble (e.g., with lead aprons, thyroid shields, or protective barriers). All products are non-sterile, non-invasive PPE intended for intact-skin contact during intermittent use. Product family includes Plano eyewear (0.75 mm Pb) and Prescription eyewear (0.75 mm Pb)

Construction: Approved frame materials across the product family include nylon, acetate, polycarbonate, and blended plastic constructions, with stainless steel hinge pins or equivalent hardware where applicable.

Protective areas: intended for occupational use in environments where ionizing-radiation–producing equipment is operated.

Category: Category III - complex

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.

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Performance:

Attenuation Properties to EN IEC 61331-1:2014 (Narrow Beam Condition)

Product Codes	Measurement/Dimension Specification	Attenuation Ratio, F (at 150 kV)	LEV mm Pb
LL-BC4	Base Curve 4/80mm x2.8mm)	31.4	0.740
LL-BC6	Base Curve 6/80mm x2.8mm)	35.5	0.777
LL-BC8	Base Curve 8/80mm x2.8mm)	34.9	0.772

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Certificate Administration Details

Technical File Reference: TF-24-A_PPE TECHNICAL FILE_2024 0529, TF-27-A

Certificate Amendment Record:

Issue Date	Comments	Internal BSI Project Number
February 2025	First issue	2797:25:30110358
November 2026	Additional product range- Radiation Protective Eyewear	2797:26: 30769821

Certificate validity:

The Certificate holder is responsible for ensuring that the Notified 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 CE 805105.

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