

# Conformity to Type based on Quality Assurance of the Production Process

This is to certify that:

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

Holds Certificate Number:

CE 805105

In respect of:

## Manufacture of Radiation Protective Clothing

on the basis that BSI carried out the quality assurance assessment under the requirements with the Regulation (EU) 2016/425 of the European Parliament and Council relating to Personal Protective Equipment Regulation (PPE) Annex VIII (Module D)

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: 2024-10-30  
Latest Issue: 2025-01-24

Effective Date: 2025-01-24  
Expiry Date: 2029-10-29



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No. CE 805105

## PPE Certificate holder:

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

## Product manufactured at the following location:

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

## Product Specification

The products covered by the scope of this Certificate conform to Technical Specifications, meeting Annex II Essential Health & Safety Requirements of the PPE Regulation 2016/425, utilizing aspects of the following standards:

Standard	Product Type
EN 61331-3:2014	Protective Devices against Diagnostic Medical X -radiation. Part 3: Protective clothing, eyewear and protective patient shields.
EN 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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Page: 2 of 3

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A member of BSI Group of Companies.

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## Certificate Amendment Record

Issue date	Comments	BSI Project No.
October 2024	First issue.	2797:24:30110403
January 2025	Update to EN ISO 13688:2013+A1:2021.	2797:25:30316973

## Certificate validity

The Certificate holder is responsible for ensuring that the Notified Body is advised of changes to any aspects of the overall quality system utilized in the manufacture of the products, failure to do so could invalidate the Certificate in respect of product manufactured after the introduction of such changes.

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