Shirley

Personal Protective Equipment Regulation (EU) 2016/425

Certificate

Module B EU Type-Examination

Manufacturer

Dr. Goos-Suprema GmbH

Brechtelstrasse 29, 69126 Heidelberg, Germany

Product Description:

X-ray Protection Garments

Product Code:

See page 2

Technical File Reference:

SH01193

Harmonised Standard(s):

EN ISO 13688:2013

Technical Specification:

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

Certificate Number: SH01193

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

First issue: 22 August 2023 Date of Issue: 22 August 2023 Expiry: 22 August 2028

Authorised by

C A Butcher
Certification Manager

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, Clonshaugh Business & Technology Park, Dublin 17, ROI
Tel: +353 (0) 01894 1448 email: info@shirley.ie website: www.shirley.ie

ISO 17065 IVNAB ACCREDITED PRODUCT CERTIFICATION DETAILED IN SCOPE REG NO 3033

Schedule of Approval
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First Issued:	**22 August 2023**	**Page No:**	**2 of 6**
Issue date:	**22 August 2023**	**Issued by:**	**Shirley® (Notified Body No. 2895)**
Expiry date:	**22 August 2028**	**Shirley® ref:**	**SH-021638**

Manufacturer: **Dr. Goos-Suprema GmbH**

Technical file ref: **SH01193**

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 Protection Garments consisting of:

EN 61331-1:2014 only

Other Devices:	**Sleeves for X-ray Aprons; Protection-Winding; X-ray Protection Cap; X-ray Breast Protection**

EN 61331-1:2014 & EN 61331-3:2014

Apron:	**Front Apron F; Front Apron CMF; Front Apron BV; Front Apron C; Wrap Around Apron Mantle RM; Wrap Around Double-Apron RD; Wrap Around Skirt and Vest Duplex RW; Duple Skirt; Duplex Vest; Wrap Around Apron Mantle jr; Front Apron F jr**
Thyroid collar:	**Thyroid-Collar SD**
Mittens:	**X-Ray Chirurgien-Gloves CH**
Gonad Aprons:	**Gonad Half Apron; Gonad Skirt**
Scrotum Shields:	**T-Shield Gonad Protection**
Ovary Shields:	**Ovary-Shield**

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Outer fabric and lining:
SupraTex; 100% Nylon with PU Coating; 130 gsm; Available in a range of colours
SupraSoft; 61% Cotton / 39% PU; 225 gsm; Available in a range of colours

Protective core materials:
SupraNorm; Lead Equivalence options: 0.25 / 0.35 / 0.50 / 1.00 mmPb; 50-150 kV
SupraLight; Lead Equivalence options: 0.25 / 0.35 / 0.50 / 1.00 mmPb; 50-110 kV

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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 Groups.

Limitations of Use

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

Observations

- Not applicable.

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Approval Documents

- Material test report No. 0054-21
- Innocuousness test report No. E-026012

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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