



Personal Protective Equipment Regulation (EU) 2016/425

# Certificate

## Module B EU Type-Examination

**Manufacturer**

**Medical Index GmbH**

Mayerhof 5, 74906 Bad Rappenau, Germany

**Product Description:**

Garments for X-ray Radiation Protection

**Product Code:**

CA Series; DA Series; SV Series; KA Series; TS Series; GP Series; Gloves; Dental Aprons; Mammary Protection

**Technical File Reference:**

522228

**Harmonised Standard(s):**

EN ISO 13688:2013/A1:2021

**Technical Specification:**

EN 61331-1:2014; EN 61331-3:2014 (exc. Mammary Protection)

**Certificate Number: SH01622**

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

**First issue:** 05 September 2024    **Date of Issue:** 05 September 2024    **Expiry:** 22 February 2029

**Authorised Signatory:**  


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





## Schedule of Approval Certificate Number: SH01622

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<b>Expiry date:</b>	<b>22 February 2029</b>	<b>Shirley® ref:</b>	<b>SH-033799</b>
<b>Manufacturer:</b>	<b>Medical Index GmbH</b>		
<b>Technical file ref:</b>	<b>522228</b>		

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**

Garments for X-ray Radiation Protection consisting of:

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

<b>Front Apron</b>	CA Series
<b>Double-sided Apron</b>	DA Series
<b>Skirt &amp; Vest</b>	SV Series
<b>Child Apron</b>	KA Series
<b>Thyroid Shield</b>	TS Series
<b>Gonad Protection</b>	GP Series
<b>Gloves</b>	
<b>Dental Aprons</b>	DSR03570; DTL07060/50; OPT07537/50

EN 61331-1:2014 Only

**Mammary Protection**

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Manufacturer:	Medical Index GmbH		
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Available in the following materials:

Outer Fabric:	<b>RP9026; 100% Polyester (200 gsm) coated with ECN3413 100% Nylon Coating</b>		
Inner Fabric:	<b>C2S; 100% Nylon (100 gsm) 100% PES</b>		
Protective Core Materials:	<b>V25LL: 0.25 mmPb Lead Equivalency;</b>	<b>V35LL: 0.35 mmPb Lead Equivalency</b>	
	<b>V25NL: 0.25 mmPb Lead Equivalency;</b>	<b>V35NL: 0.35 mmPb Lead Equivalency</b>	
	<b>0.50 mmPb Lead Equivalency will comprise of two layers of the 0.25 mmPb materials</b>		

### Explanation of Product Codes and Sizing

CA = Coat Apron; 5 digits for the size, e.g. 12060 = 120 cm length, 60 cm width at the hip; 2 digits for the lead equivalent thickness of the front side: 25 = 0.25 mmPb, 35 = 0.35 mmPb, 50 = 0.50 mmPb

DA = Double Side Apron; 6 digits for the size, e.g. 120117 = 120 cm length, 117 cm girth at the hip, 2 digits for the lead equivalent thickness of the front side: 50 = 0.50 mmPb

SV = Skirt and Vest; 6 digits for the size, e.g. 125117 = 125 cm length of the skirt and length of the vest, 117 cm girth at the chest of the vest, 2 digits for the lead equivalent thickness of the front side: 50 = 0.50 mmPb

KA = Kids Apron; 5 digits for the size, e.g. 05045 = 50 cm length, 45 cm width at the hip; 2 digits for the lead equivalent thickness of the front side: 50 = 0.50 mmPb

TS = Thyroid Shield; 5 digits for the size, e.g. 0045 = 4 cm height at the thyroid and 5 cm at the sternum; 2 digits for the lead equivalent thickness of the front side: 0.35 = 0.35 mmPb, 50 = 0.50 mmPb

GP = Gonad Protection; 5 digits for the size, e.g. 02025 = 20 cm length and 25 cm width; 2 digits for the lead equivalent thickness of the front side: 50 = 0.50 mmPb

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<b>Technical file ref:</b>	<b>522228</b>		

**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 with variations and adaptations based on user requirements.

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

**Limitations of Use**

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

**Observations**

- Not applicable.

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<b>Manufacturer:</b>	<b>Medical Index GmbH</b>		
<b>Technical file ref:</b>	<b>522228</b>		

**Approval Documents**

- Ergonomic Assessment test report Nos. 522228/A1/CS; 522228/A2/CS
- Lead Equivalence test report Nos. 2015070344\_2; 2015050150\_8; 2015070344\_1; 2015050150\_7
- Oeko-tex Certificate. 18.HCN.48353

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<b>Manufacturer:</b>	<b>Medical Index GmbH</b>		
<b>Technical file ref:</b>	<b>522228</b>		

### 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



Personal Protective Equipment Regulation (EU) 2016/425

# Quality Assurance Certificate

## Module D

**Manufacturer**

**Medical Index GmbH**

Mayerhof 5, 74906 Bad Rappenau, Germany

**Scope:**

CE marking of X-ray protective clothing and accessories

**Certificate Number: SH01621**

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

**First issue:** 14 August 2024      **Date of Issue:** 14 August 2024      **Expiry\*:** 14 August 2027

**Authorized by:**



Certification Manager

**\*Subject to continued compliance and audit.**

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





**Schedule of Approval**  
**Certificate Number: SH01621**

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<b>Expiry date:</b>	<b>14 August 2027</b>	<b>Shirley® ref:</b>	<b>SH-032301</b>
<b>Manufacturer:</b>	<b>Medical Index GmbH</b>		

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 quality assessment procedures for the manufacturing sites identified below, which were found to be in compliance with Module D "conformity to type based on quality assurance of the production process" of the Regulation, subject to any conditions in the schedule attached hereto.

This certificate authorises the use of the Mark of Conformity (the 'CE mark'), together with the number of the Notified Body involved in the production control phase (2895) once the manufacturer has issued a Declaration of Conformity according to Article 15 of the Regulation.

**Places of Production**

An der Zeil 1, 74906 Bad Rappenau, Germany

**Approval Documents**

Shirley/JP/Medical Index/01.2024;  
Shirley/LE/Medical Index/05.2024

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<b>Expiry date:</b>	<b>14 August 2027</b>	<b>Shirley® ref:</b>	<b>SH-032301</b>

**Manufacturer:** Medical Index GmbH

### Terms and Conditions associated with the issue of this Quality Assurance 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 above.
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:
  - a) Permit ongoing surveillance and access to documentation and records, and access to the relevant equipment, location(s), area(s), personnel and clients subcontractors.
  - b) 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.
  - c) Allow participation of observers during surveillance audits when requested.
6. The client must only make claims consistent with the scope of certification,
7. The client must not make any misleading or unauthorised comments regarding the certified product or the certification body.
8. 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®.
9. The client must comply with the requirements for the use of the notified body number as detailed below.
10. Changes to a client's product design, manufacturing processes, operations, location, management team or resource provision that could have an impact on the certified product shall be immediately notified to Shirley®.
11. 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.
12. 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 Manufacturer shall have continuous surveillance of Factory Production Control carried out by a Notified Body and a re-certification of Factory Production Control every three years.

### 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 Quality System 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.
4. The EC mark consists of the letters 'CE', in the form given in Annex II of Regulation (EC) No. 765/2008, followed by Shirley®'s notified body number.

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

END OF REPORT