BTTG

TESTING • CERTIFICATION • AUDITING

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; Mammary Protection

Technical File Reference:

522228

Harmonised Standard(s):

EN ISO 13688:2013

Technical Specification:

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

Certificate Number: 523312/1

Issued by: BTTG™ (Notified Body No. 0338 for Regulation (EU) 2016/425)

First issue: 22 February 2019 Date of Issue: 22 February 2019 Expiry: 22 February 2024

Authorised by

J Lumb

Certification Officer

Authorised by

C A Butcher

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:

BTTG™, Unit 6 Wheel Forge Way, Trafford Park, Manchester, M17 1EH, United Kingdom

Tel: +44 (0)161 876 4211 email: ppe@bttg.co.uk website: www.bttg.co.uk

Schedule of Approval
Certificate Number: 523312/1

First Issued:	**22 February 2019**	**Page No:**	**2 of 6**
Issue date:	**22 February 2019**	**Issued by:**	**BTTG™ (Notified Body No. 0338)**
Expiry date:	**22 February 2024**	**BTTG™ ref:**	**E-005940**

Manufacturer: **Medical Index GmbH**

Technical file ref: **522228**

BTTG™, 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 BTTG™, 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

Front Apron	CA Series
Double-sided Apron	DA Series
Skirt & Vest	SV Series
Child Apron	KA Series
Thyroid Shield	TS Series
Gonad Protection	GP Series
Gloves	

EN 61331-1:2014 Only

Mammary Protection

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Available in the following materials:

Outer Fabric:	**RP9022; 100% Polyester (200 gsm) coated with ECN3413 100% Nylon Coating**	
Inner Fabric:	**C2S; 100% Nylon (100 gsm)**	
Protective Core Materials:	**V25LL: 0.25 mmPb Lead Equivalency;**	**V35LL: 0.35 mmPb Lead Equivalency**
	V25NL: 0.25 mmPb Lead Equivalency;	**V35NL: 0.35 mmPb Lead Equivalency**
	0.50 mmPb Lead Equivalency will comprise of two layers of the 0.25 mmPb materials	

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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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 adaptions 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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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

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Terms and Conditions associated with the issue of this EU Type-Examination Certificate

1. This certificate is issued subject to BTTG™'s standard terms of business.
2. Production is limited to the site(s) listed in the manufacturer's Technical File, copies of which are held by the manufacturer and BTTG™, and not to any other production site(s).
3. The client must implement appropriate changes as notified by BTTG™.
4. The client must ensure the certified product is representative of the ongoing manufactured product.
5. 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 BTTG™ 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 BTTG™.
9. The client must comply with the requirements for the use of the notified body number as detailed below.
10. Any change to the product or quality manual / quality plan shall be immediately notified to BTTG™.
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. This certificate remains the property of BTTG™ and will be withdrawn if any of the conditions attached to its issue are not complied with.
12. 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).
13. 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 BTTG™ 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 BTTG™ Notified Body Number with other products or systems or schemes and with claims or information not contained in the BTTG™ document.

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

END OF SCHEDULE