

DECLARATION UE DE CONFORMITE

Je soussignée, Madame Sandrine COLOMBEL, agissant en qualité de Responsable Qualité de la société **MEDIPROTEC**, 9 rue du Poitou – 91220 Brétigny sur Orge, déclare que l'équipement de protection individuel neuf décrit ci-après :

0813832	COMBINAISON SMS BLANCHE 50 G/M ² – TAILLE M à XXL
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Est conforme au modèle de combinaison ayant fait l'objet de la déclaration UE de conformité de type n° :
CE 0954220001-00-00

délivrée par l'organisme notifié n°**0624 CENTROCOT**, Centro Tessile Cottoniero e Abbigliamento S.p.A.
P.zza Sant'Anna, 2 - 21052 Busto Arsizio (VA) – Italie.

Et est soumis à la procédure d'évaluation de la conformité au type sur la base du contrôle interne de la production et de contrôles supervisés du produit à des intervalles aléatoires (Module C2) sous la surveillance de l'organisme notifié N°**0624 CENTROCOT**, Centro Tessile Cottoniero e Abbigliamento S.p.A. P.zza Sant'Anna, 2 - 21052 Busto Arsizio (VA) – Italie.

Les combinaisons sont conformes aux dispositions du règlement UE 2016/425 – Catégorie III protection contre les risques mortels ou dommages irréversibles. Elles sont conçues pour la protection contre les risques chimiques. Elles sont fabriquées en conformité avec les normes harmonisées :

- EN ISO 13688 :2013
- EN 13034 :2005+A1 :2009
- EN ISO 13982-1 :2004 + A1 :2010
- EN 1073-2 :2002
- EN 1149-5 :2008
- EN 14325 :2004

La présente déclaration de conformité est établie sous la seule responsabilité du fabricant.

Signé pour et au nom de **MEDIPROTEC**.

Fait à Brétigny sur Orge, le 24/06/2021.

Sandrine COLOMBEL

Responsable Qualité



ANNEXE 1

0813832-M	LOTS :
0813832-L	LOTS : 2001127
0813832-XL	LOTS : 2001126, 2001127, 2100121,
0813832-XXL	LOTS : 2001127, 2100121



Nous changeons d'identité, pas de métier.



CENTROCOT
Innovation experience



Notified Body n. 0624

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EU TYPE-EXAMINATION CERTIFICATE

No CE 0954220001 -00 -00

According to "Regulation (EU) 2016/425 of the European Parliament and of the Council" of 9th March 2016 on Personal Protective Equipment and repealing Council Directive 89/686/EEC

Centro Tessile Cotoniero e Abbigliamento S.p.A.
P.zza Sant'Anna, 2 - 21052 Busto Arsizio (VA) - Italia

EEC Notified Body N° 0624

- in view of the firm's application submitted on: 30th November 2021;
- in view of the positive results of the Technical File verification submitted by the manufacturer together with the above mentioned request;
- in view of the manufacturer's declaration stated in the Technical File attached to the above mentioned request
- having verified that technical specification of design and manufacture is in compliance with basic requirements specified in annex II of Regulation (EU) 2016/425 and that technical manufacturing documentation is in compliance with above mentioned specifications;
- in view of the positive test results carried out on the basic model representative of production according to paragraph 4 of annex V of Regulation (EU) 2016/425;

Issues to:

PROMOSAC MEDIPROTEC S.a.s.
9 Rue du Poitou – ZI Maison Neuve, 91220 Bretigny Sur Orge - FRANCE

the EU Type-Examination Certificate concerning the following PPE model:

COVERALL to protect against chemical hazards
0813832

Category: **III** (third)

The model of Personal Protective Equipment is subject to conformity to type assessment according to Section 19 c) of Regulation (EU) 2016/425 (Module C2 or D)

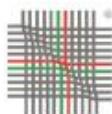


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PRD N° 163B LAB N° 0033
LAT N° 226
Signature of CA, IP and EAC
Mutual Recognition Agreements



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Notified Body n. 0024

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Basic type description

0813832

One-piece coverall white color, with hood, zipper at front opening covered by flap, elastic cuffs, ankles, hood and waist.
Coverall with hood elasticated wrists, ankles & waist, double flap over the zipper
Fabric:
SMS Polypropylene 100%, 50 g/m² white colour



Variations description

No variations

Sizes

From M to XXL

Standards

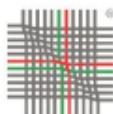
EN ISO 13688:2013	Protective clothing - general requirements
EN ISO 13982-1:2004 +A1:2010	Protective clothing for use against solid particulates - Part 1: Performance requirements for chemical protective clothing providing protection to the full body against airborne solid particulates
EN 13034:2005+A1:2009	Protective clothing against liquid chemicals - Performance requirements for chemical protective clothing offering limited protective performance against liquid chemicals
EN 1073-2:2002	Protective clothing against radioactive contamination - Requirement and test methods for non-ventilated protective clothing against particulate radioactive contamination
EN 1149-5:2018	Protective clothing - Electrostatic properties - Part 5; Material performance and design requirements
EN 14325:2004	Protective clothing against chemicals - Test methods and performance

EU type-examination certificate No. CE 0954220001-00-00 PROMOGAC MEDIPROTEC Page 2 / 3



PRD N° 163B LAB N° 0033
LAF N° 226
Signatory of EA, IAF and ILAC
Mutual Recognition Agreements

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classification of chemical protective clothing materials, seams, joins and assemblages

Performance levels

EN ISO 13982-1	Type 5	protection against airborne solid particulates
EN 13034	Type 6	limited protective performance against light spray, liquid aerosol or low pressure, low volume splashes
EN 1073-2	Class 2	Total Inward Leakage

Tests

The test results are included in the report: 16RA01019, 18RA08976, 18RA07725

Marking

The following information are listed on the label inside the garment:

- EC marking
- Company name
- Article code
- Standards
- Standardized pictograms
- Maintenance symbols
- PPE category

Validity

- The validity of this certificate is subject to the validity of the certificate n. 0784180483-00-04 this is the extension of. On expiration date it will be responsibility of the Manufacturer to ask for the renewal.
- Any change on model and materials object of this Certificate shall be notified and then approved by Centrocot.

This certificate must be filed by the manufacturer and must be shown, if requested, to the Body that performs controls or to the surveillance authority

Busto Arsizio,

Issue date:
12th January 2022

Expiry date:
31st July 2023



General Manager
Dr. Grazia Cerini



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PRD N° 163B LAB N° 0033
LAT N° 226
Signature of EA, IAF and ILAC
Notified Institution Addressed