

Prophylactic

Prophylactic type 5/6 classic coverall

www.prophylactic.com.tr

DISPOSABLE LAMINATED PROTECTIVE COVERALL "The best protection for health"

TYPE 5/6



Protective coverall with one-piece hood

Hooded three-dimensional cut and elastic band around the face opening with one piece, it is more convenient to increase the face shape and protection effect.

Stitched Tape edges

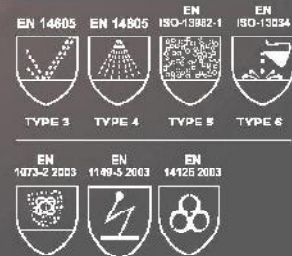
Each seam is sealed with tape. Internal elastic band is applied to the waist. These sewing style applications provide better protection.

Elastic cuff

Elastic cuff application provides a tighter and better protection.



Protective Clothing Category III



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Technical Specification Sheet

Prophylactic type 5/6 classic coverall

Key Features

- Disposable coverall, with hood, zip front opening covered by self adhesive flap, elastic cuff, ankles, hood and waist. Cut and sewn seams.
- Very little fiber
- Excellent barrier against dry particles and certain limited liquid chemical splashes

Material Composition

- Fabric : 18 gsm polietilen film
2 gsm hotmelt glue
35 gsm polypropylene
gsm: gram/m²

Country of Origin

- Made in the Turkey with globally sourced materials

Use For

- Intended to be worn by operating room protect both the surgical patient and the operating room personnel from transfer of microorganisms, body fluids, and particulate material



Do Not Use For

- DO NOT use in industrial settings
- DO NOT use for gases or vapors (i.e. anesthetic gases such as isoflurane or vapors.
- DO NOT use in any manner not indicated in the User instructions

Approvals and Standards

- EN ISO 13688:2013
- EN ISO 13982-1:2004 +A1:2010
- EN 13034:2005 +A1:2009
- EN 1073-2:2002
- EN 14126:2003 + AC:2004
- EN 1149-5:2018

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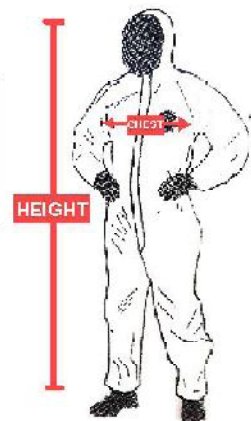
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SIZE	CHEST	HEIGHT
L	68	160
XL	70	164



EU TYPE EXAMINATION CERTIFICATE

Certificate No: 2163-PPE-1209

BOİNC TEKSTİL SANAYİ VE TİCARET LİMİTED ŞİRKETİ
Beştelsiz Mahallesi Semiha Şakir Caddesi No: 63/67 Zeytinburnu İstanbul / TURKEY

It is certified that the manufacturer's technical file (Dated 20.06.2020) and the PPE product, detailed below, have been assessed and found to meet the applicable Essential Health and Safety Requirements in Annex II of Regulation (EU) 2016/425 based on the evaluation on technical documentation and relevant test reports.

Identification of the Personal Protective Equipment

Brand Name: PROPHYLACTIC, **Model:** BNC8734

Protective coverall manufactured from laminated polypropylene non-woven fabric with hood, inside bound seams, elastic cuff, ankle and waist, zipper and zipper flap. The coverall is available in 6 nominal sizes.

The following harmonised standards have been applied:

- EN ISO 13688:2013, (General requirements for protective clothing)
- EN ISO 13982-1:2004/A1:2010, (Chemical protective clothing providing protection to the full body against airborne solid particulates) Type 5, limited wear life clothing,
- EN 13034:2005+A1:2009, (Chemical protective clothing offering limited protective performance against liquid chemicals) Type 6, limited wear life clothing,
- EN 14126:2003/AC:2004, (Protective clothing against infective agents) for Type 5-B, 6-B

Here by the manufacturer is allowed to use notified body number (2163) and can fix CE mark, as shown below, on the Category III product models given above, with the below requirements;

- Issuing an appropriate EU Declaration of Conformity according to **Personal Protective Equipment Regulation (EU) 2016/425 Annex 9**.
- Ongoing successful performance in fulfilment of the requirements set out in **Personal Protective Equipment Regulation (EU) 2016/425** and harmonised standards, ensured by assessments based on **Annex 7 (Module C2) or Annex 8 (Module D)** of the regulation

This certificate is initially issued on **05/08/2020** and will be valid for 5 years from the issue date.



Suat KAÇMAZ
UNIVERSAL CERTIFICATION
Director



EU DECLARATION OF CONFORMITY

MANUFACTURER

BOINC TEKSTİL SANAYİ VE TİCARET LİMİTED ŞİRKETİ
Beştelesiz Mahallesi Semiha Şakir Caddesi No: 63/67 Zeytinburnu İstanbul / TURKEY

PRODUCT DESCRIPTION

Brand Name: PROPHYLACTIC, Model: BNC8734

Protective coverall manufactured from laminated polypropylene non-woven fabric with hood, inside bound seams, elastic cuff, ankle and waist, zipper and zipper flap. The coverall is available in 6 nominal sizes.

Type 5 - Providing Protection to the Full Body against Airborne Solid Particulates

Type 6 - Offering Limited Protective Performance against Liquid Chemicals

Type 5-B, Type 6-B, Protective clothing against infective agents

The Manufacturer declares on his sole responsibility that the product above is, under conditions of normal use and conditions defined by the Manufacturer, safe and meets all the necessary legal conditions and requirements. The product is a personal protective equipment that is intended for single use and solely in accordance with the Manufacturer's instructions.

The Conformity is assessed with the following mechanism:

- Complies with EU 2016/425 Personal Protective Equipment Regulation establishing technical requirements for Category III products,
- Complies with Technical harmonised standards in accordance the Essential Health and Safety Requirements referenced to EU 2016/425 PPE Regulation, EN ISO 13688:2013, EN 14126:2003/AC:2004, EN ISO 13982 1:2004/A1:2010, EN 13034:2005+A1:2009
- All required tests referred in above standards are conducted,
- Complies with other relevant harmonized legislation and community standards
- For the assessment of conformity the EU Type Examination certificate is issued, after all technical evaluations for conformity to the regulation and harmonised standards conducted under supervision of:
 - UNIVERSAL CERTIFICATION, SURVEILLANCE SERVICES and TRADE Co,
Notified Body number 2163

MARKING, LABELLING

Marking, labelling and user information are prepared in accordance with EU 2016/425 Personal Protective Equipment Regulation and EN 14126. The information is supplied with the product considering EN ISO 15223-1:2016 and EN 1041:2008+A1:2013.

MEASURES TO ENSURE CONFORMITY

The Manufacturer declares that he has taken all necessary measures to ensure the conformity of products placed on the market with technical documentation and technical requirements for this type of product.

Murat FIRAT
General Manager
08/08/2020

BOINC TEKSTİL
SAN. VE TİC. LTD. ŞTİ.
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