

EU DECLARATION OF CONFORMITY

MANUFACTURER

GENÇ TAAHHÜT GİYİM TEKSTİL İNŞAAT SAN. VE TİC. LTD. ŞTİ.

Refahiye Mah. 281. Sk. Selim apt. Zemin KatNo:9/2 Haliliye / Şanlıurfa TURKEY Branch Manufacturing
Site: General Ali Rıza Gürcan Caddesi Merter İş Merkezi No:2/2 I Merter İstanbul TURKEY

PRODUCT DESCRIPTION

GNC-2215 Model, Protective Clothing against infective agents;
Type 3 Providing Protection to the Full Body against Liquid Jets
Type 4- Providing Protection to the Full Body against Liquid Sprays
with the following classification;

Resistance to penetration by contaminated liquids under hydrostatic pressure: Class 3
Resistance to penetration by infective agents due to mechanical contact with substances containing
contaminated liquids: Class 3
Resistance to penetration by contaminated liquid aerosols: Class 1
Resistance to penetration by contaminated solid particles: Class 2

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 EN 14126:2003/AC:2004, EN ISO 13982-1:2004/A1:2010, EN 13034:2005+A1:2009, EN 14605:2005 + A1:2009
- All required tests referred in above standards are conducted,
- European Regulation (EU) 2017/745 and 93/42/EEC Medical Device Directive class 1 Annex VII establishing technical requirements for medical devices, in effective wording.
- Complies with other relevant harmonized legislation and community standards
- **The model of Personal Protective Equipment is subject to Section 19 c) of Regulation (EU) 2016/425 (Module C2 or D)**
- **EU Type-Examination Certificate Nr.2163-PPE-1784 GENC TAAHHUT.**
- 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, by;
 - o UNIVERSAL CERTIFICATION, SURVEILLANCE SERVICES and TRADE Co, as
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 we have 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.

 **GENÇ TAAHHÜT GİYİM TEKSTİL
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ABDULVAHAP GENÇ

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