

# EU TYPE EXAMINATION CERTIFICATE

Certificate No: 2163-PPE-1341

## İBİŞLER TEKSTİL SANAYİ VE DIŞ TİCARET A.Ş.

Orhangazi Mahallesi Tunç Caddesi No:5 34358 Esenyurt ISTANBUL / TURKEY

It is certified that the manufacturer's technical file (Dated 25.08.2020) 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.

#### Subcontracted Manufacturer Sites

Site 1: Fatsa OSB Mah. 101. Sokak No:11/A Fatsa ORDU / TURKEY

#### Identification of the Personal Protective Equipment Brand Name: A&Z MED, Model: OL1-2028

Isolation gown, as a protective clothing for the part of body Type [PB]-6-B, manufactured from blue polypropylene non-woven fabric, inside bound seams, with belt. The gown is available in 5 nominal sizes.

#### The following harmonised standards have been applied:

EN ISO 13688:2013, (General requirements for protective clothing)

EN 13034:2005+A1:2009, (Chemical protective clothing offering limited protective performance against liquid chemicals) Type PB [6], limited life clothing,

EN 14126:2003/AC:2004, (Protective clothing against infective agents) for Type PB [6]-B, limited life

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 25/08/2020 and will be valid for 5 years from the issue date.



Suat KAÇMAZ
UNIVERSAL CERTIFICATION
Director



# **EU DECLARATION OF CONFORMITY**

### MANUFACTURER

# İBİŞLER TEKSTİL SANAYİ VE DIŞ TİCARET A.Ş.

Orhangazi Mahallesi Tunç Caddesi No:5 34358 Esenyurt ISTANBUL / TURKEY

Subcontracted Manufacturer Sites
Site 1: Fatsa OSB Mah. 101. Sokak No:11/A Fatsa ORDU / TURKEY

Identification of the Personal Protective Equipment

Brand Name: A&Z MED, Model: OLI-2028

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İlhan İBİŞ General Manager 25/08/2020

