



**BAKBAK**  
MAKİNE



	HEIGHT	CHEST
S	164 - 170 cm	84 - 92 cm
M	167 - 176 cm	92 - 100 cm
L	174 - 181 cm	100 - 108 cm
XL	179 - 187 cm	108 - 115 cm
XXL	186 - 194 cm	115 - 124 cm
3XL	194 - 200 cm	124 - 132 cm
4XL	200 - 206 cm	132 - 140 cm

**HEIGHT**

**CHEST**

\* İstenilen Ölçü ve Tasarımda Ürün Üretebiliriz.

\* We are ready to produce customized designs and dimensions.

1. Material: laminated non-woven fabric, total density (non-woven material + external lamination material) min 60g/m<sup>2</sup>.
2. Protective tape along the entire length of the seams.
3. Boots integral part of the overalls, provided with elastic at the ankle.
4. Hood with elastic and stitched flap or flap that comes as an integral part of the coverall hood for chin closure. Closure of hood flap by fixing with adhesive tape.
5. To close with a zipper, the slider of the zipper is secured with a lock, to avoid accidental opening. Compulsory zipper plate covered with adhesive tape attachment on the distal portion of the plate, along the entire length of the zipper, to protect against the penetration of infectious agents through the zipper material.
6. Sleeve secured with finger loop to prevent the sleeve from slipping out of the gloves.
7. One pair of additional booties made of laminated spon bond material, for additional foot protection.
8. The coverall provides protection according to AAMI PB 70 performance level 4, or (EN 14126-B) and EN 14605, or equivalent.
9. Ensures freedom of movement.
10. Individual packaging with the inscription of the size and model of the jumpsuit. Disposable product. Available sizes L, XL, 2XL, 3 XL.

1. Material: laminated non-woven, minimum density 50 g/m<sup>2</sup>.
2. Boots integral part of the overalls, provided with elastic at the ankle.
3. Hood with elastic and stitched flap or flap that comes as an integral part of the coverall hood for chin closure. Closure of hood flap by fixing with adhesive tape.
4. It closes with a zipper, the slider of the zipper is equipped with a lock, to avoid accidental opening. Flap zipper protective.
5. The coverall provides biological protection against dangerous substances and infectious microbial agents, it is impermeable to water and organic liquids (including in the form of aerosols), alternatively, the coverall provides protection against penetration by blood and body fluids.
6. Ensures freedom of movement.
7. Individual packaging with the inscription of the size and model of the jumpsuit. Disposable product. Available sizes: L, XL, 2XL, 3XL.
8. The coverall provides protection according to AAMI PB 70 performance level 4, or (EN 14126-B) and (EN 13034 or EN 14605), or equivalent.

**BAKBAK**  
MAKİNE SANAYİ VE TİCARET LİMİTED ŞİRKETİ  
Sanayi Mh. 60013 Cd. No: 4 ŞEHİTKAMİL - GAZİANTEP  
Tel: (0342) 235 4 777 • Sp. Tic. Sic. No: 132 119 0016  
Tic. Sic. No. 62593 • Mersis No: 0132119001600001

**BAKBAK MAKİNE SANAYİ VE TİCARET LİMİTED ŞİRKETİ**

Küşget Sanayi Mahallesi 60013 Nolu Cadde No: 4

ŞEHİTKAMİL / GAZİANTEP / TÜRKİYE

Tel: +90 532 782 92 22 Web: www.bakbakmakine.com E-mail: medical@bakbakmakine.com

## Declaration of Conformity

The manufacturer or his authorized representative established in the Community:

Business name: Bakbak Makine Sanayi ve Ticaret Limited Şirketi

Address: Sanayi Mahallesi 60013 Nolu Cadde No 4 Şehitkamil / GAZİANTEP

Country: TURKEY

Declares that the new PPE described hereafter:

Equipment name: Disposable Non-Sterile Coverall with/without Boot Cover

Make: BAKBAK MEDICAL

Type or model: T2-C56

Serial number: T2-C56-6000 Series

Relevant supplementary information: Coveralls with Hoodie and with/without Boot Cover made of 55GSM Polyethylene Laminated Polypropylene Non-Woven fabric.

are in conformity with the provisions of Council Directive 89/686/EEC and, where such is the case, with the following national standard transposing harmonized standard:

EN 13795 SINGLE USE AND REUSABLE DRAPES (INCLUDING EQUIPMENT COVERS AS STERILE FIELD), SURGICAL GOWNS AND CLEAN AIR SUITS

(EU) 2016/425 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL OF 9 MARCH 2016 ON PERSONAL PROTECTIVE EQUIPMENT AND REPEALING COUNCIL DIRECTIVE 89/66/EEC

93/42/EEC MEDICAL DEVICE DIRECTIVE

Is identical to the PPE which is the subject of EC certificate of conformity

No 20.02.310-CE issued by:

Notified Body name: INSPECT Uluslararası Belgelendirme ve Gözetim Hizmetleri Tic. Ltd. Sti.

Address: Altay Çeşme M. Gülcihan S. No:19/A Maltepe İSTANBUL

Country: TURKEY

Description of intervention: CE Certification

Number EU type: 20.02.319CE

Place and date of issue (of this Doc):

April 4<sup>th</sup>, 2020 – Gaziantep/TURKEY



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Tic. Sic. No: 32593 • Mersis No: 0132119001600001

# AB Tip İnceleme Sertifikası EU Type-Examination Certificate

Belge No / Certificate No	: 122-20-02
Belgelendirme Tarihi - Bir Sonraki Belge Tarihi / Certification Date / Certificate Validity Date	: 13.01.2021-.13.01.2026
Belge Geçerlilik Tarihi / Document Validity Period	: 5 Yıl/5 Years
Firma Unvanı ve Adresi / Company Name and Address	: BAKBAK MAKİNE SAN. VE TİCARET LİMİTED ŞİRKETİ Küsget San. Mah. 60013 Nolu Cd. No: 4 ŞEHİTKAMİL/GAZİANTEP/ TÜRKİYE
Ürün Adı /Modeller / Product Name / Models	: T2-C56 Serial number: T2-C56-6000 Series
Direktifi / Directive	: 2016/425 REGULATION
Modülü/Kategori / Module / Category	: B MODÜLÜ / KATEGORİ III MODULE B CATEGORY III
Test Rapor No/ları / Test Report No	: MNA M2020-00804 -00561
Ürün Tipi / Product Type:	
- EN ISO 13688 Koruyucu giyecekler - Genel özellikler / Protective clothing - General requirements	
- EN 13034+ A1 Sıvı Kimyasallara Karşı Koruyucu Giysi (Tip 6-B) / Protective Clothing Against Liquid Chemicals (Type 6-B)	
- EN ISO 13982-1 Katı Parçacıklara Karşı Koruyucu Giysi (Tip 5-B)/ Protective Clothing For Use Against Solid Particulates (Type 5-B)	
- EN 14605+A1 Koruyucu Giyecekler - Sıvı Kimyasal Maddelere Karşı (Tip 3-B, Tip 4-B) / Protective clothing against liquid chemicals (Type 3-B, Type 4-B)	
- EN 14126 Koruyucu Giyecekler - Patojen Organizmalara Karşı / Protective Clothing - Performance Requirements And Tests Methods For Protective Clothing Against Infective Agents	

Ürünün Malzeme Bilgisi / Product Material Information : DC-BM-001 model ürünleri kaplamalı kumaş kullanılarak imal edilmiştir./ DC-BM-001 model products are manufactured using coated fabric

Volkan AKIN  
24.12.2020

Karar Verici / Approver



Okan AKEL  
24.12.2020

Şirket Müdürü / General manager



# G-CERTI Certificate

G-CERTI hereby certifies that

**BAKBAK MAKİNE SANAYİ VE TİCARET LTD.ŞTİ.**

**KÜSGET SANAYİ MAH.60013 NOLU CAD. NO:4  
ŞEHİTKAMİL/GAZİANTEP TÜRKİYE**

has been audited and certified as meeting the requirements of Scope of registration

**ISO 13485:2016 Medical Devices -- Quality Management Systems**

**Maske, önlük ve tulum imalatı satışı ve ihracatı**

Manufacturing, selling and exporting of mask, gown and protective cloth

Certificate No : GCTU-0100-MD

Initial Date : 10.09.2021

Issue Date : 10.09.2021

Expiry Date : 09.09.2024

Valid period : 10.09.2021-09.09.2024

Signed for and on behalf of G-CERTI  
President TK Çiçi

