



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.

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

BAKBAK MAKİNE SANAYİ VE TİCARET LİMİTED ŞİRKETİ
Küsget 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 4th, 2020 – Gaziantep/TURKEY



BAKBAK
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BAKBAK MAKİNE SANAYİ VE TİCARET LİMİTED ŞİRKETİ
Sanayi Mh. 60013 Cd. No: 4 Şehitkamil, GAZİANTEP
Tel: (0342) 235 4 777 • Sanitkamil V.D. No:132 119 0016
Tic. Sic. No: 32593 • Mersis No:0132119001600001

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. Sep. 2020

Issue Date : 10. Sep. 2020

Expiry Date : 09. Sep. 2023

Valid period : 10. Sep. 2020 ~ 09. Sep. 2021

Signed for and on behalf of G-CERTI
President UK Choi



MSCB-113

BAKBAK
BAKBAK MAKİNE SANAYİ VE TİCARET LTD. ŞTİ.
Sanayi Mh. 60013 Cad. No: 4 Şehitkamil - GAZİANTEP
Tel:(0342) 236 4 777 - Şehitkamil V.D. No:132 119 0016
Tic.Sic.No: 52593 • Mersis No:0132119001600001



ACCREDITED

ISO 13485



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

