

## 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



**BAKBAK**  
M A K İ N E  
BAKBAK MAKİNE SANAYİ VE TİCARET LİMİTED ŞİRKETİ  
Sanayi Mh. 60013 Cd. No: 4 Şehitkamil, GAZİANTEP  
Tel: (0342) 235 4 777 • Şehitkamil 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.  
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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

