



## KAF GRUP SAĞLIK HİZMETLERİ SANAYİ VE TİCARET LİMİTED ŞİRKETİ

MERKEZ ADRES: ATAKENT MAH. 221 SK. NO:3A ROTA OFFİCE A BLOK KAT:14 D:82-83  
KÜÇÜKÇEKMECE / İSTANBUL / TÜRKİYE

FABRİKA ADRES 1: HADIMKÖY MAH. DENİZKIZI SOK. NO: 4/5 ARNAVUTKÖY / İSTANBUL / TÜRKİYE

FABRİKA ADRES 2: BARDAKÇI MAH. TEKNOKENT SK. NO:3 TUŞBA / VAN / TÜRKİYE

*Certificate No: QA/TR/9001/1520*

The above mentioned organization has implemented and applies a quality management system within the scope specified below and its compliance with the relevant standard has been approved by ALBERK QA TECHNIC.

### ISO 9001:2015

STERILE NON STERILE MEDICAL DEVICES AND CONSUMABLES (BODY CLEANING, HAND CLEANING WIPES, HAIR BONNET, INCONTINENCE BODY CARE AND PERINEUM WIPES, ULTRASOUND GEL, ADHESIVE REMOVER SPRAY, EEG PASTE, ALCOHOL-FREE FOAM HAND SANITISER, MOUTHWASH, CONTAINING ALKALINE NEUTRALISER AND ENZYME SOLUTION, STRETCHER AND TABLE COVER, MEDICAL DEVICE SURFACE DISINFECTANTS, HIGH LEVEL MEDICAL DEVICE DISINFECTANTS, STERILE LUBRICANT GEL, ELECTRODE, ELECTROSURGICAL PEN TYPE AND TWEEZERS TYPE FORCEPS, ELECTRODE TYPE SURGICAL PENS, SCALPEL ULTRASONIC SURGICAL SYSTEM DEVICES AND PROBES AND CABLE DESIGN) PRODUCTION AND SALES

EA CODE: 23

This certificate is valid as long as the company fulfills the requirements of the ISO 9001:2015 standard and bears its responsibility towards ALBERK QA TECHNIC.

*Certificate Issue Date: 26.01.2024*

*Certificate Validity Date: 25.01.2025*

*Certificate First Issue Date: 26.01.2024*

*Certification cycle / End Date: 3 years/25.01.2027*

*Certificate Revision Number and Date: 00 / 26.01.2024*

General Manager  
Latif Murat YILMAZ



ALBERK QA TECHNIC INTERNATIONAL TECHNICAL  
CONTROL AND CERTIFICATION CORP.

Barbaros Mah. Al Zambak S. Varyap Meridian A Blok K:19  
ATAŞEHİR İSTANBUL

Tel : 0216 572 49 10-11-12

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# ISO 14001:2015



## Kapsam/Scope

STERILE NON STERILE MEDICAL DEVICES AND CONSUMABLES (BODY CLEANING, HAND CLEANING WIPES, HAIR WASH CAP, INCONTINENCE BODY CARE AND PERINEAL WIPES, ULTRASOUND GEL, ADHESIVE REMOVER SPRAY, EEG PASTE, ALCOHOL-FREE FOAM HAND DISINFECTANT, ORAL CARE SWAB, SOLUTION CONTAINING ALKALINE NEUTRALIZER AND ENZYME, STRETCHER AND TABLE COVER, MEDICAL DEVICE SURFACE DISINFECTANTS, HIGH LEVEL MEDICAL DEVICE DISINFECTANTS, STERILE LUBRICANT GEL, ELECTRODES, ELECTROSURGICAL PEN TYPE AND TWEEZER TYPE FORCEPS, ELECTRODE TYPE SURGICAL PEN, SCALPEL ULTRASONIC SURGERY SYSTEM DEVICE AND PROBES AND CABLE DESIGN) PRODUCTION AND SALES

# SERTİFİKA CERTIFICATE

## KAF GRUP SAĞLIK HİZMETLERİ SANAYİ VE TİCARET LİMİTED ŞİRKETİ

MERKEZ ADRES: ATAKENT MAH. 221 SK. NO:3A ROTA OFFİCE A BLOK KAT:14 D:82-83 KÜÇÜKÇEKMECE/İSTANBUL/TÜRKİYE  
FABRİKA ADRES 1: HADIMKÖY MAH. DENİZKIZI SOK. NO: 4/5 ARNAVUTKÖY/İSTANBUL/TÜRKİYE  
FABRİKA ADRES 2: BARDAKÇI MAH. TEKNOKENT SK. NO:3 TUŞBA/VAN/TÜRKİYE

Bu sertifika ile yukarıda adı geçen kuruluşun Çevre Yönetim Sistemi gerekliliklerini karşıladığı tasdik olunur.  
This is to certify that the above mentioned Company meets the requirement of Environmental Management System.

IAF K. - Kategori - Teknik Alan / IAF C. - Category -Technical Area	7-14-17-18-23
Uygulanabilirlik Bildirgesi / SOA	-
Sertifika No / Certification Number	MTS-36134
İlk Kayıt Tarihi / Registration Date	16.02.2024
Basım Tarihi / Issue Date	16.02.2024
Geçerlilik Tarihi / Expiry Date	15.02.2025
Belgelendirme Periyodu / Certification Period	3 yıl / 3 years
Revizyon / Revision	000

- Bu sertifika kuruluşun belgelendirme şartlarına uyması ve yılda en az bir kez yapılacak olan gözetim denetimlerinin başarılı geçmesi halinde üç yıllık sertifikasyon periyodu bitiş tarihine kadar geçerlidir.
- Sertifikanın geçerlilik durumu resmi internet adresimizden sorgulanabilir.
- This certificate is valid until the end of the three-years certification period if the organization complies with the certification requirements and the surveillance audits to be carried out at least once a year are completed successfully.
- The validity of the certificate can be checked on the our official website.

Sigmacert Global  
Onay / Approval  
Ankara

T 01 Rev 0029 19.2023

**SİGMACERT ULUSLARARASI BELGELENDİRME EĞİTİM VE TEST HİZMETLERİ LTD. ŞTİ.**

📍 Bahçekapı Mahallesi Sanayi Bulvarı Şaşmaz Business Plaza No: 18/25 Etimesgut/Ankara/Türkiye  
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MSCB-136



## KAF GRUP SAĞLIK HİZMETLERİ SANAYİ VE TİCARET LİMİTED ŞİRKETİ

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FABRİKA ADRES 2: BARDAKÇI MAH. TEKNOKENT SK. NO:3 TUŞBA / VAN / TÜRKİYE

*Certificate No: AQ/ /45001/1406*

The above mentioned organization has implemented and applies a occupational health and safety management system within the scope specified below and its compliance with the relevant standard has been approved by ALBERK QA AKADEMİ.

### ISO 45001:2018

STERILE NON STERILE MEDICAL DEVICES AND CONSUMABLES (BODY CLEANING, HAND CLEANING WIPES, HAIR BONNET, INCONTINENCE BODY CARE AND PERINEUM WIPES, ULTRASOUND GEL, ADHESIVE REMOVER SPRAY, EEG PASTE, ALCOHOL-FREE FOAM HAND SANITISER, MOUTHWASH, CONTAINING ALKALINE NEUTRALISER AND ENZYME SOLUTION, STRETCHER AND TABLE COVER, MEDICAL DEVICE SURFACE DISINFECTANTS, HIGH LEVEL MEDICAL DEVICE DISINFECTANTS, STERILE LUBRICANT GEL, ELECTRODE, ELECTROSURGICAL PEN TYPE AND TWEEZERS TYPE FORCEPS, ELECTRODE TYPE SURGICAL PENS, SCALPEL ULTRASONIC SURGICAL SYSTEM DEVICES AND PROBES AND CABLE DESIGN) PRODUCTION AND SALES

EA CODE: 23

This certificate is valid as long as the company fulfills the requirements of the ISO 45001:2018 standard and bears its responsibility towards ALBERK QA AKADEMİ.

*Certificate Issue Date: 26.01.2024*

*Certificate Validity Date: 25.01.2025*

*Certificate First Issue Date: 26.01.2024*

*Certification cycle / End Date :3 years/25.01.2027*

*Certificate Revision Number and Date :00 / 26.01.2024*

**General Manager**  
**Latif Murat YILMAZ**

ALBERK QA PERSONEL BELGELENDİRME  
VE AKADEMİ HİZMETLERİ A.Ş.  
Barbaros Mah. Al Zambak S. A Blok K:19/172 NO:2  
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## KAF GRUP SAĞLIK HİZMETLERİ SANAYİ VE TİCARET LİMİTED ŞİRKETİ

MERKEZ ADRES: ATAKENT MAH. 221 SK. NO:3A ROTA OFFİCE A BLOK KAT:14 D:82-83  
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FABRİKA ADRES 2: BARDAKÇI MAH. TEKNOKENT SK. NO:3 TUŞBA / VAN / TÜRKİYE

*Certificate No: AQ/GMP/0040*

The above mentioned organization has implemented and applies a  
within the scope specified below and its compliance with the relevant standard has been approved by ALBERK QA TECHNIC.

### GMP

STERILE NON STERILE MEDICAL DEVICES AND CONSUMABLES (BODY CLEANING, HAND CLEANING WIPES,  
HAIR BONNET, INCONTINENCE BODY CARE AND PERINEUM WIPES, ULTRASOUND GEL, ADHESIVE  
REMOVER SPRAY, EEG PASTE, ALCOHOL-FREE FOAM HAND SANITISER, MOUTHWASH, CONTAINING  
ALKALINE NEUTRALISER AND ENZYME SOLUTION, STRETCHER AND TABLE COVER, MEDICAL DEVICE  
SURFACE DISINFECTANTS, HIGH LEVEL MEDICAL DEVICE DISINFECTANTS, STERILE LUBRICANT GEL,  
ELECTRODE, ELECTROSURGICAL PEN TYPE AND TWEEZERS TYPE FORCEPS, ELECTRODE TYPE SURGICAL  
PENS, SCALPEL ULTRASONIC SURGICAL SYSTEM DEVICES AND PROBES AND  
CABLE DESIGN) PRODUCTION AND SALES

This certificate is valid as long as the company fulfills the requirements of the GMP standard and bears its responsibility towards ALBERK QA TECHNIC.

*Certificate Issue Date: 26.01.2024*  
*Certificate First Issue Date: 26.01.2024*

*Certificate Validity Date: 25.01.2025*  
*Certification cycle / End Date: 3 Years /25.01.2027*

*Certificate Revision Number and Date: 00/26.01.2024*

Genel Müdür  
Latif Murat Yılmaz

ALBERK QA PERSONEL BELGELENDİRME  
VE AKADEMİ HİZMETLERİ A.Ş.  
Barbaros Mah. Al Zambak S. A Blok  
K:19/172 NO:2  
ATAŞEHİR İSTANBUL  
Tel : 0216 572 49 10-11-12  
Fax : 0216 572 49 14





# CERTIFICATE

## KAF GRUP SAĞLIK HİZMETLERİ İNŞ. SAN. VE TİC. LTD. ŞTİ.

MERKEZ ADRESİ: ATAKENT MAH. 221 SOK. NO:3A ROTA OFFİCE A BLOK KAT:14 D:82-83  
KÜÇÜKÇEKMECE / İSTANBUL / TÜRKİYE

1. FABRİKA ADRESİ: HADIMKÖY MAH. DENİZ KIZI SOK. NO 4/5  
ARNAVUTKÖY / İSTANBUL / TÜRKİYE

2. FABRİKA ADRESİ: BARDAKÇI MAH. TEKNOKENT SOK. NO:3  
TUŞBA / VAN / TÜRKİYE

*Has been assessed and found to comply with the requirements of:  
Denetlenmiş ve aşağıdaki standardın gerekliliklerine uygunluğu görülmüştür:*

### ISO 13485:2016

*Medical Devices-Quality Management System is applicable to:  
Tıbbi Cihazlar Kalite Yönetim Sistemi*

PRODUCTION AND SALES OF STERILE, NON STERILE MEDICAL DEVICES AND CONSUMABLES (DESIGN OF BODY CLEANSING, HAND CLEANSING WIPES, HAIR WASHCAP, INCONTINENCE BODY CARE AND PERINEAL WIPES, ULTRASOUND GEL, ADHESIVE REMOVER SPRAY, EEG PASTE, ALCOHOL-FREE FOAM HAND DISINFECTANT, MOUTH CARE SWAB, ALKALINE NEUTRALISING AND ENZYME CONTAINING SOLUTION, STRETCHER AND TABLE COVER, MEDICAL DEVICE SURFACE DISINFECTANTS, HIGH LEVEL MEDICAL DEVICE DISINFECTANTS, STERILE LUBRICANT GEL, ELECTRODE, ELECTRO SURGICAL PEN TYPE AND TWEEZERS TYPE FORCEPS, ELECTRODE TYPE SURGICAL PEN, SCALPEL ULTRASONIC SURGICAL SYSTEM DEVICE AND PROBES AND CABLE)

STERİL, NON STERİL TIBBİ CİHAZ VE SARF MALZEMELERİN (VÜCUT TEMİZLEME, EL TEMİZLEME MENDİLİ, SAÇ BONESİ, İNKONTİNANS VÜCUT BAKIMI VE PERİNE MENDİLLERİ, ULTRASON JELİ, YAPIŞKAN SÖKÜCÜ SPREY, EEG PASTASI, ALKOL İÇERMİYEN KÖPÜK EL DEZENFEKTANI, AĞIZ BAKIM SWABI, ALKALI NÖTRALİZAN VE ENZİM İÇEREN SOLÜSYON, SEDYE VE TABLA ÖRTÜSÜ, TIBBİ CİHAZ YÜZEY DEZENFEKTANLARI, YÜKSEK DÜZEY TIBBİ CİHAZ DEZENFEKTANLARI, STERİL KAYGANLAŞTIRICI JEL, ELEKTROD, ELEKTRO CERRAHİ KALEM TİPİ VE CIMBIZ TİPİ FORCEPSLER, ELEKTROT TİP CERRAHİ KALEM, SCALPEL ULTRASONİK CERRAHİ SİSTEM CİHAZI VE PROBLARI VE KABLO TASARIMI) ÜRETİMİ VE SATIŞI

Certificate Number: 2024/MDQMS/000511  
Belge Numarası: 2024/MDQMS/000511

Initial Certification Date: 05.03.2024  
İlk Belgelendirme Tarihi: 05.03.2024

Certification Period: 3 Years  
Belgelendirme Periyodu: 3 Yıl

Certificate Validity Date: 04.03.2025  
Belge Geçerlilik Tarihi: 04.03.2025

IQR Sertifikasyon Onayı



IQR ULUSLARARASI BELGELENDİRME HİZMETLERİ LTD.ŞTİ.

Beşevler Mah. Kocayunus Sk. No:3 Arslan Han Plaza K:2 Nilüfer / BURSA

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