



# Certificate

**ISO 13485 : 2016**

**KAF GRUP SAĞLIK HİZ. İNŞ.  
SAN. VE TİC. LTD. ŞTİ.**

Head Office: Atakent Mah. 221. Sk. Rota Office A Blok No: 3 A İç Kapı No: 83

Küçükçekmece /İstanbul /TURKEY

Istanbul Manufacturing Address: Hadımköy Mahallesi Deniz Kızı Sok. No: 4 / 5  
Arnavutköy / İstanbul/TURKEY

This certificate shows that the medical devices - quality management system (EN ISO 13485:2016) of the above company was approved by PCA Certification for the following scope, the validity of the certificate depends on the company's pass the annual surveillance audits and company's maintenance the related management system conditions according to international accreditation criteria

## SCOPE

Manufacturing and sales of barrier cream wash gloves, washcap-shampoo cap, incontinence body wipes and perineal cloths; body and perineal are cleansing wipes, splints, fixers / plaster tapes and tube fixers, ultrasound ecg gel, eeg paste, alcohol-free foam hand sanitizer, oral care swab, oral care set swab, alkali, neutralizer and enzyme containing solution, stretcher paper roll

### GROUP CODE

A

**Certificate No** : TC-75264  
**Registration Date** : 24.03.2020  
**Reissue Date** : 29.03.2022  
**Expiry Date** : 23.03.2023  
**Certificate Period** : 3 Years (From the date of registration)  
**Exclusion** : 4.1.5 / 4.1.6 / 7.3 / 7.5.3 / 7.5.4 /  
7.5.9.2 / 7.5.10 / 8.3.4



PCA Certification Approval

PCA Sertifikasyon Hizmetleri Limited Şirketi  
Orta Mah. Ordu Sk. İzpark C Blok No:26/23 Kartal / İSTANBUL  
Tel: +90 216 510 63 48-49 Pbx Faks: +90 216 517 63 49  
www.pca-tr.com info@pca-tr.com

FR.86 Rev.4





**TRB**  
INTERNATIONAL

# CERTIFICATE

## KAF GRUP SAĞLIK HİZMETLERİ SANAYİ VE TİCARET LİMİTED ŞİRKETİ

MAIN ADDRESS: ATAKENT MAH.221.SOK ROTA OFFICE A BLOK NO:3A D:82-83 KÜÇÜKÇEKMECE İSTANBUL  
FACTORY ADDRESS: HADIMKÖY MAH.DENİZ KIZI SOK.NO:4/5 ARNAVUTKÖY İSTANBUL

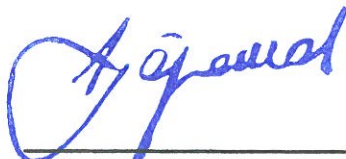
## ISO 9001:2015

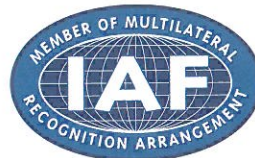
PRODUCTION AND SALES OF STERILE AND NON-STERILE MEDICAL DEVICES AND CONSUMABLES  
(BODY CLEANER, HAND CLEANING WIPES, HAIR RESTRAINT ETC)

This certificate is valid for 3 years on condition that surveillance audits are carried out before the period of each year in accordance with the accreditation rules. With this certificate, the holder of the certificate has been audited on the address mentioned above by TRB Certification Body in accordance with the condition and requirements of the license contract and it has been registered that the company satisfies the conditions of the standard. This certificate is valid as long as the certificate holder follows TRB certification rules and the certificate is seen as valid on [www.trb.com.de](http://www.trb.com.de) web site certificate inquiry section.

Certification Number : DE-QC-1914  
Date of Issue : 15.02.2021  
Expiry Date : 14.02.2023  
Certification Period : 3 Years (2. Year)  
Printing Number : 01



  
General Manager



Deutsche  
Akkreditierungsstelle  
D-ZM-19486-01-00



**TRB**  
INTERNATIONAL

# CERTIFICATE

## KAF GRUP SAĞLIK HİZMETLERİ İNŞAAT SANAYİ VE TİCARET LİMİTED ŞİRKETİ

MAIN ADDRESS: ATAKENT MAH.221.SOK ROTA OFFICE A BLOK NO:3 A D:82-83 KÜÇÜKÇEKMECE İSTANBUL  
FACTORY ADDRESS: HADIMKÖY MAH.DENİZ KIZI SOK.NO:4/5 ARNAVUTKÖY İSTANBUL

## GMP

PRODUCTION AND SALES OF STERILE AND NON-STERILE MEDICAL DEVICES

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Certification Number : DE-GMP-051  
Date of Issue : 15.01.2021  
Expiry Date : 14.01.2023  
Certification Period : 3 Years (2. Year)  
Printing Number : 01



  
General Manager







**TRB**  
INTERNATIONAL

# CERTIFICATE

## KAF GRUP SAĞLIK HİZMETLERİ SANAYİ VE TİCARET LİMİTED ŞİRKETİ

MAIN ADDRESS: ATAKENT MAH.221.SOK ROTA OFFICE A BLOK NO:3A D:82-83 KÜÇÜKÇEKMECE İSTANBUL  
FACTORY ADDRESS: HADIMKÖY MAH.DENİZ KIZI SOK.NO:4/5 ARNAVUTKÖY İSTANBUL

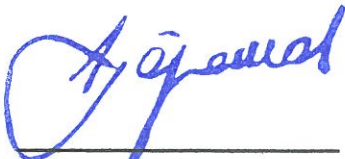
## ISO 14001:2015

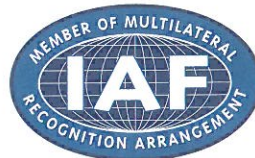
PRODUCTION AND SALES OF STERILE AND NON-STERILE MEDICAL DEVICES AND CONSUMABLES  
(BODY CLEANER, HAND CLEANING WIPES, HAIR RESTRAINT ETC)

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Certification Number : DE-EC-1914  
Date of Issue : 15.02.2021  
Expiry Date : 14.02.2023  
Certification Period : 3 Years (2. Year)  
Printing Number : 01



  
General Manager



Deutsche  
Akkreditierungsstelle  
D-ZM-19486-01-00



**TRB**  
INTERNATIONAL

# CERTIFICATE

## KAF GRUP SAĞLIK HİZMETLERİ SANAYİ VE TİCARET LİMİTED ŞİRKETİ

MAIN ADDRESS: ATAKENT MAH.221.SOK ROTA OFFICE A BLOK NO:3A D:82-83 KÜÇÜKÇEKMECE İSTANBUL  
FACTORY ADDRESS: HADIMKÖY MAH.DENİZ KIZI SOK.NO:4/5 ARNAVUTKÖY İSTANBUL


## ISO 45001:2018

PRODUCTION AND SALES OF STERILE AND NON-STERILE MEDICAL DEVICES

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Certification Number : DE-SC-1914  
Date of Issue : 01.03.2021  
Expiry Date : 28.02.2023  
Certification Period : 3 Years (2. Year)  
Printing Number : 01



  
General Manager

**EU Medical Device Regulation 2017/745****Declaration of Conformity**

<b>Manufacturer Name(*)</b>	KAF GRUP SAĞLIK HİZMETLERİ İNŞ. SAN. VE TİC. LTD. ŞTİ		
<b>Manufacturer Address(*)</b>	Atakent Mah. 221 Sk. No:3A Rota Office A Blok Kat:14 D:83 Küçükçekmece/İstanbul/Turkey		
<b>Manufacturer Individual Identity No.</b>			
<b>If the product is produced by someone else by the manufacturer, the Manufacturer's Name and Address (* if any)</b>			
<b>Name of the product(*)</b>	Barrier Cream Incontinence Wipes Barrier Cream Incontinence Perineal Cloths Wash Gloves With Barrier Cream		
<b>Catalog/Reference No. (*)</b>	<b>Product Name</b>	<b>Catalog No</b>	
	Barrier Cream Incontinence Wipes (8 pcs)	KAF G49	
	Barrier Cream Incontinence Wipes (12 pcs)	KAF G01	
	Barrier Cream Incontinence Wipes (25 pcs)	KAF G08	
	Barrier Cream Incontinence Wipes (50 pcs)	KAF G07	
	Barrier Cream Incontinence Wipes (100 pcs)	KAF G50	
	Barrier Cream Incontinence Perineal Cloths (8 pcs)	KAF G51	
	Barrier Cream Incontinence Perineal Cloths (12 pcs)	KAF G06	
	Barrier Cream Incontinence Perineal Cloths (25 pcs)	KAF G02	



	Barrier Cream Incontinence Perineal Cloths (50 pcs)	KAF G05	
	Barrier Cream Incontinence Perineal Cloths (100 pcs)	KAF G52	
	Wash Gloves With Barrier Cream	KAF G16	
Purpose of usage(*)	<p>ONECARE Barrier Creamy Incontinence Wipes and Perineal Cloths are used to create a barrier layer to protect the incontinence-related skin of patients with special needs, such as those with reduced mobility, bedridden and intensive care patients, by cleaning urine and feces contact from external factors. It prevents skin damage that may occur due to pH change and irritation in the body.</p> <p>ONECARE Wash Gloves with Barrier Cream are used to create a barrier layer to protect the incontinence-related skin of patients with special needs, such as those with reduced mobility, bedridden and intensive care patients, by cleaning urine and feces contact from external factors. It prevents skin damage that may occur due to pH change and irritation in the body.</p>		
Basic UDI-DI(*)	Catalog No	Basic UDI-DI	
	KAF G49	868256095KAFG49KJ	
	KAF G01	868256095KAFG01JN	
	KAF G08	868256095KAFG08K4	
	KAF G07	868256095KAFG07K2	
	KAF G50	868256095KAFG50K3	
	KAF G51	868256095KAFG51K5	
	KAF G06	868256095KAFG06JY	
	KAF G02	868256095KAFG02JQ	
	KAF G05	868256095KAFG05JW	
	KAF G52	868256095KAFG52K7	
	KAF G16	868207900KAFG16DL	
Product Classification / Classification Rule(*)	Class 1		
GMDN Code(*)	46205		
EMDN Code (*After activation)	Z120113		
Conformity Assessment Procedure(*)	<input checked="" type="checkbox"/>	ANNEX-IV (Annex II & III)	Declaration of conformity
	<input type="checkbox"/>	ANNEX-IX (CHAPTER I & III)	Quality management system
	<input type="checkbox"/>	ANNEX-IX (PART II)	Technical Documentation Mod.
	<input type="checkbox"/>	ANNEX-X	Type Examination

**KAF GRUP SAĞLIK HİZMETLERİ İNŞ. SAN. TİC. LTD. ŞTİ**  
Atakent Mahallesi 221 Sk. No:3A Rota Office A Blok Kat 14 D:83  
Küçükçekmece/İstanbul/Türkiye

(Additions executed in the product evaluation are marked)	<input type="checkbox"/>	ANNEX-XI (PART A)	Production Quality Assurance
	<input type="checkbox"/>	ANNEX-XI (PART B)	Product Verification
Notified Body Name and Number (**)			
EU Certificate No and Description Start/Effective date (**)			
Other EU Legislation / Common Specifications / Harmonized Standards to which the product complies	<b>Harmonized Standards</b>		
	EN ISO 13485:2016	EN ISO 10993-5: 2009	EN ISO 10993-1: 2020
	EN ISO 15223-1: 2021	EN ISO 10993-10: 2021	EN ISO 20417: 2021

(\*) Sections beginning with are required.

(\*\*) The conformity assessment is mandatory for products made by the notified body.

As a company **KAF GRUP SAĞLIK HİZMETLERİ İNŞ. SAN. TİC. LTD. ŞTİ**, we declare under our sole responsibility that the devices covered by this declaration comply with the Regulation (EU) 2017/745 of the European Parliament and of the Council on Medical Devices and that the requirements specified in the Regulation are fulfilled for these devices.

Signature Date and Place : 05.08.2022

Effective Date (if applicable) :

Signatory : Gökmen Aydin

Mission : General Manager

[Signature and Seal/Stamp]

KAF GRUP SAĞLIK HİZMETLERİ  
İNŞ. SAN. TİC. LTD. ŞTİ.  
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A Blok Kat 14 D:83 Küçükçekmece/İSTANBUL  
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