



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
İstanbul Manufacturing Address: Hadimköy 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.96 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

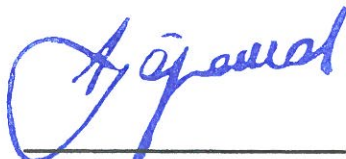
ISO 9001:2015

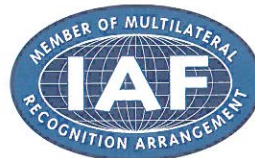
PRODUCTION AND SALES OF STERILE AND NON-STERILE MEDICAL DEVICES AND CONSUMABLES
(BODY CLEANER, HAND CLEANING WIPES, HAIR RESTRAINT ETC)

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 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





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

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 web site certificate inquiry section.

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

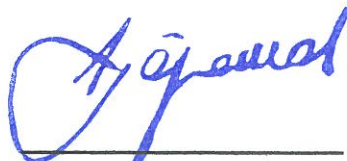
ISO 14001:2015

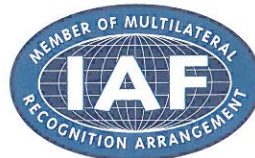
PRODUCTION AND SALES OF STERILE AND NON-STERILE MEDICAL DEVICES AND CONSUMABLES
(BODY CLEANER, HAND CLEANING WIPES, HAIR RESTRAINT ETC)

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 web site certificate inquiry section.

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





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

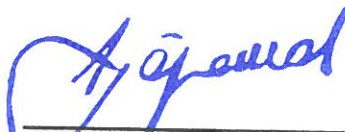
ISO 45001:2018

PRODUCTION AND SALES OF STERILE AND NON-STERILE MEDICAL DEVICES

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 web site certificate inquiry section.

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



THE REPUBLIC OF TURKEY
MINISTRY OF HEALTH
TURKISH MEDICINES AND MEDICAL DEVICES AGENCY

Certificate No: 222489

Date of Issue : 26 April 2022

CERTIFICATE OF FREE SALE

To whom it may concern,

It is hereby certified that the products detailed in the attached schedule, which are manufactured by "KAF GRUP SAĞLIK HİZMETLERİ İNŞAAT SANAYİ VE TİCARET LİMİTED ŞİRKETİ" (Atakent Mh. 221 Sk. No:3/A KÜÇÜKÇEKMECE İSTANBUL), have been affixed with the CE mark in accordance with Medical Device Directives of the European Union (EU) and are freely sold in Turkey and EU.

This certificate is issued to be given to the relevant competent authorities of other countries and is valid for 36 months from the date of issue.

Yours sincerely,

Ömer Faruk KURU

Head of Medical Devices

Registration and Coordination Department

This certificate consists of 2 page/s and 8 products. The products listed in the attached schedule are registered from the date of issuance of this certificate and information about the current status of these products is accessible through

<https://utsuygulama.saglik.gov.tr/UTS/vatandas#/vatTibbiCihazListele>.



Date of Issue : 26 April 2022

PRODUCT SCHEDULE

#	Barkod	Brand	Label Name	Reference No / Version / Model	GMDN Code
1	8682022062215	ONECARE	BARRIER CREAM INCONTINENCE PERINEAL CLOTHS	KAFG02	46205
2	8682022062246	ONECARE	BARRIER CREAM INCONTINENCE PERINEAL CLOTHS	KAFG06	46205
3	8682022062208	ONECARE	BARRIER CREAM INCONTINENCE WIPES	KAFG01	46205
4	8682022062222	ONECARE	BODY CARE SET	KAF G04	46205
5	8682022062260	ONECARE	BARRIER CREAM INCONTINENCE WIPES	KAFG08	46205
6	8682022062253	ONECARE	BARRIER CREAM INCONTINENCE WIPES	KAFG07	46205
7	8682022062239	ONECARE	BARRIER CREAM INCONTINENCE PERINEAL CLOTHS	KAFG05	46205
8	8682079003155	ONECARE	WASH GLOVES WITH BARRIER CREAM	KAFG16	46205

End of product schedule.



KAFGRUP

SAĞLIK HİZMETLERİ

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

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

Manufacturer Name(*)	KAF GRUP SAĞLIK HİZMETLERİ İNŞ. SAN. VE TİC. LTD. ŞTİ		
Manufacturer Address(*)	Atakent Mah. 221 Sk. No:3A Rota Office A Blok Kat:14 D:83 Küçükçekmece/İstanbul/Turkey		
Manufacturer Individual Identity No.			
If the product is produced by someone else by the manufacturer, the Manufacturer's Name and Address (* if any)			
Name of the product(*)	Barrier Cream Incontinence Wipes Barrier Cream Incontinence Perineal Cloths Wash Gloves With Barrier Cream		
Catalog/Reference No. (*)	Product Name	Catalog No	
	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

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

Atakent Mahallesi 221 Sk. No:3A Rota Office A Blok Kat:14 D:83

Küçükçekmece/Istanbul/Turkey

EU Medical Device Regulation 2017/745

Declaration of Conformity

Manufacturer Name(*)	KAF GRUP SAĞLIK HİZMETLERİ İNŞ. SAN. VE TİC. LTD. ŞTİ											
Manufacturer Address(*)	Atakent Mah. 221 Sk. No:3A Rota Office A Blok Kat:14 D:83 Küçükçekmece/Istanbul/Turkey											
Manufacturer Individual Identity No.												
If the product is produced by someone else by the manufacturer, the Manufacturer's Name and Address (* if any)												
Authorized European Representative	Anxietas Ug. Industriestrasse 43, 50389 Berzdorf Köln/GERMANY Köln HRB: 106071 info@anxietas.de											
Name of the product(*)	WANCARE ULTRASOUND ECG GEL											
Catalog/Reference No.(*)	<table><thead><tr><th>Name of the Product</th><th>Catalog No</th></tr></thead><tbody><tr><td>WANCARE ULTRASOUND ECG GEL 1000ml</td><td>KAF G31</td></tr><tr><td>WANCARE ULTRASOUND ECG GEL 500 ml</td><td>KAF G31-1</td></tr><tr><td>WANCARE ULTRASOUND ECG GEL 250ml</td><td>KAF G31-2</td></tr><tr><td>WANCARE ULTRASOUND ECG GEL 5 lt</td><td>KAF G31-3</td></tr></tbody></table>	Name of the Product	Catalog No	WANCARE ULTRASOUND ECG GEL 1000ml	KAF G31	WANCARE ULTRASOUND ECG GEL 500 ml	KAF G31-1	WANCARE ULTRASOUND ECG GEL 250ml	KAF G31-2	WANCARE ULTRASOUND ECG GEL 5 lt	KAF G31-3	
Name of the Product	Catalog No											
WANCARE ULTRASOUND ECG GEL 1000ml	KAF G31											
WANCARE ULTRASOUND ECG GEL 500 ml	KAF G31-1											
WANCARE ULTRASOUND ECG GEL 250ml	KAF G31-2											
WANCARE ULTRASOUND ECG GEL 5 lt	KAF G31-3											
Purpose of usage(*)	It cuts the air between the skin and the probe in all kinds of Ultrasonography, Doppler, EKG, Exercise Test applications, and ensures that the ultrasonography waves come to the device screen more clearly and uninterruptedly.											
Basic UDI-DI(*)	<table><tbody><tr><td>KAF G31</td><td>8682079003KAFG319T</td></tr><tr><td>KAF G31-1</td><td>868207900KAFG31-1N4</td></tr><tr><td>KAF G31-2</td><td>868207900KAFG31-2N6</td></tr><tr><td>KAF G31-3</td><td>868207900KAFG31-3N8</td></tr></tbody></table>	KAF G31	8682079003KAFG319T	KAF G31-1	868207900KAFG31-1N4	KAF G31-2	868207900KAFG31-2N6	KAF G31-3	868207900KAFG31-3N8			
KAF G31	8682079003KAFG319T											
KAF G31-1	868207900KAFG31-1N4											
KAF G31-2	868207900KAFG31-2N6											
KAF G31-3	868207900KAFG31-3N8											
Product Classification / Classification Rule(*)	Class 1											

GMDN Code(*)	15321		
EMDN Code (*After activation)	A108002		
Conformity Assessment Procedure(*) (Additions executed in the product evaluation are marked)	<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
	<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	Harmonized Standards		
	EN ISO 13485:2016	EN ISO 10993-5: 2009	EN ISO 10993-1: 2020
	EN ISO 15223-1: 2021	EN ISO 10993-10: 2013	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 : 27.07.2022

Effective Date (if applicable) :

Signatory : Gökmen AYTIN

Mission : General Manager

[Signature and Seal/Stamp]

KAF GRUP SAĞLIK HİZMETLERİ
İNŞAAT SANAYİ VE TİC. LTD. ŞTİ
Atakent Mah. 221 Sk. No:3A Rota Office
A Blok D:83 Küçükçekmece / İSTANBUL
Tel: 0212 471 42 00 Fax: 0212 471 42 01
Halkal N.Ü. 486 053 8804

Document No	Issue Date	Revision No	Revision Date
TD. 03.51	10.06.2019	04	23.02.2022

**EC DECLARATION OF CONFORMITY****Medical Devices Directive 93/42/EEC - Medical Devices Directive (93/42/AT)**

Company Name	:	KAF GRUP SAĞLIK HİZMETLERİ İNŞ. SAN. TİC. LTD. ŞTİ
Authorized Person / Title	:	Gökmen Aytin / General Manager
Head Office Address	:	Atakent Mahallesi 221 Sk. No:3A Rota Office A Blok Kat 14 D:83 Küçükçekmece/İstanbul/TURKEY
Production Address	:	Bardakçı Mah. Teknokent Sk. No:3 Tuşba/VAN
Phone Number	:	+90 212 471 42 00
Web	:	www.kafgrup.com
Mail	:	info@kafgrup.com
Brand Information	:	ONEGEL

as, the models and GMDN Codes of our **Onegel Lubricat Gel With Lidocaine (Sterile)** products specified in the **TD.03.22 Product Model and GMDN Code Table**;

Product List

Reference Code	Product Name	Substance	Volume	GMDN CODE	Class
KAF G27-6	ONEGEL LUBRICANT GEL WITH LIDOCAINE	Lidocaine HCL 2%, Chlorhexidine Gluconate 0,05%, Methyl Hydroxybenzoate, Propyl Hydroxybenzoate, Propylene Glycol, Hydroxyethyl Cellulose, Purified Water.	6 ml	37717	III

EC DECLARATION

Document No	Issue Date	Revision No	Revision Date
TD. 03.51	10.06.2019	04	23.02.2022

KAF G27-11	ONEGEL LUBRICANT GEL WITH LIDOCAINE	Lidocaine HCL 2%, Chlorhexidine Gluconate 0,05%, Methyl Hydroxybenzoate, Propyl Hydroxybenzoate, Propylene Glycol, Hydroxyethyl Cellulose, Purified Water.	11 ml	37717	III
KAF G27-12,5	ONEGEL LUBRICANT GEL WITH LIDOCAINE	Lidocaine HCL 2%, Chlorhexidine Gluconate 0,05%, Methyl Hydroxybenzoate, Propyl Hydroxybenzoate, Propylene Glycol, Hydroxyethyl Cellulose, Purified Water.	12,5 g	37717	III

2017/745/EU Medical Device Regulation

EN ISO 13485:2016
EN 1041:2008+A1:2013
EN ISO 10993-6:2016
EN ISO 10993-12:2021
EN ISO 14644-3:2019
EN ISO 11607-2:2020
EN ISO 11137-1:2015
EN 868-5:2019
ASTM F 1929-15
EN 14698-2:2003
European Pharmacopoeia (Ph. Eur.)
10th Edition
Meddev 2.7.1 rev 2016

EN ISO 15223-1:2021
EN ISO 62366-1:2015
EN ISO 10993-10:2013
EN ISO 14644-1:2015
EN ISO 14644-4:2001
EN ISO 11737-1:2018
EN ISO 11137-2:2015
EN ISO 10993-5:2009
ASTM F 88/F88 M
EN ISO 7886-1:2018
Meddev 2.12-1 rev.2013

EN ISO 14971:2019
EN ISO 10993-1: 2020
EN ISO 10993-3:2014
EN ISO 14644-2:2015
EN ISO 11607-1:2020
EN ISO 11737-2:2020
EN 556-1:2001/AC:2006
ASTM F 1980-16
EN ISO 14698-1:2003
USP 43-NF 38
Meddev 2.12-2 rev 2:2012

Manufactured to harmonized standards, and we declare that it complies with the provisions of the

Document No	Issue Date	Revision No	Revision Date
TD. 03.51	10.06.2019	04	23.02.2022

Medical Device Directive 93/42/EEC Annex II (4)
Full Quality Assurance Certificate
Class III
(93/42/AT Annex IX, Rule 13 ve Rule 5)

Authorized European Representative: Anxietas Ug,
Industriestrasse 43,
50389 Berzdorf
Köln/GERMANY
Köln HRB: 106071
info@anxietas.de

GMND Code	37717- Transurethral instrument lubricant
GMDN Description	A lubricant designed to facilitate the manipulation of a surgical instrument within the body during endoscopic processes of the urinary canal. This device cannot be reutilized after application.

Notified Body	: TÜRK STANDARTLARI ENSTİTÜSÜ
Notified Body Address	: Necatibey Cad. No:112 06100 Bakanlıklar/ANKARA
Notified Body Identity No	: 1783
Design Certificate No	: 1783-MDD-239
Issue Date of Design Certificate	: 24.05.2021
Validity Date of Design Certificate	: 26.05.2024
Design Inspection Report Number	: 2203-MDD-173/2020-02
Quality Certificate No	: 1783-MDD-238
Issue Date of Quality Certificate	: 24.05.2021
Validity Date of Quality Certificate	: 26.05.2024
Quality Inspection Report Number	: 2203-MDD-173/2020-02
Company Declaration Date	: 23.02.2022
Place of Declaration	: İSTANBUL-TURKEY
Declarant	: Gökmen Aytin / GENERAL MANAGER
Approval	:  KAF GRUP SAĞLIK HİZMETLERİ İNŞAAT SANAYİ VE TİC. LTD. ŞTİ. Atakent Mh. 221. Sk. No:3A Rofa Office A Blok D:53 K.Çekmece / İSTANBUL Tel: 0212 471 42 00 Fax: 0212 471 42 01 Halkalı V.D.: 486 053 3864