PCA

PARTNERS CERTIFICATE ASSURANCE

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: 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 / flaster 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

IAS ACCREDITED
Management Systems Certification Body
MSCB-103

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

Digitally signed by Granaci Boris
Date: 2022.12.07 16:23:50 EET
Reason: MoldSign Signature
Location: Moldova

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

MEMBER OF MULTILATERAL RECOGNITION ARRANGEMENT IAF

DAkkS Deutsche Akkreditierungsstelle D-ZM-19486-01-00

Pfannenstiel 17, D-88677 Markdorf-Deutschland
Telefon: 0049-7544-7440623 Fax: 0049-7544-7440629 web: www.trb.com.de E-mail: info@trb.com.de

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

TRB

General Manager

Pfannenstiel 17, D-88677 Markdorf-Deutschland
Telefon: 0049-7544-7440623 Fax: 0049-7544-7440629 web: www.trb.com.de E-mail: info@trb.com.de

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

MEMBER OF MULTILATERAL RECOGNITION ARRANGEMENT IAF

DAkkS Deutsche Akkreditierungsstelle D-ZM-19486-01-00

Pfannenstiel 17, D-88677 Markdorf-Deutschland
Telefon: 0049-7544-7440623 Fax: 0049-7544-7440629 web: www.trb.com.de E-mail: info@trb.com.de

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

Pfannenstiel 17, D-88677 Markdorf-Deutschland
Telefon: 0049-7544-7440623 Fax: 0049-7544-7440629 web: www.trb.com.de E-mail: info@trb.com.de

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.

UTS
ÜRÜN TAKİP SİSTEMİ

Address: Sögütözü Mahallesi, 2176. Sokak No:5 06520 Çankaya/ANKARA
Phone: +90 312 218 30 00 Fax: +90 312 218 34 60 https://www.titck.gov.tr

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.

Product list to Free Sales Certificate no. 222489

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/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 Küçükcekmece/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)	
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*

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/İstanbul/Türkiye

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(*)

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.
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.

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(*)

☒	ANNEX-IV (Annex II & III)	Declaration of conformity
☐	ANNEX-IX (CHAPTER I & III)	Quality management system
☐	ANNEX-IX (PART II)	Technical Documentation Mod.
☐	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/İstanbul/Türkiye

(Additions executed in the product evaluation are marked)	☐	ANNEX-XI (PART A)	Production Quality Assurance
	☐	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: 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 Aytin

Mission : General Manager

[Signature and Seal/Stamp]

KAF GRUP SAĞLIK HİZMETLERİ
SAAT SANAYİ VE TİC.LTD.ŞTİ.
Atakent Mh. 221 Sk. No:3A Rota Office
Tel: 0212 [illegible] Fax: 0212 471 42 01
Halkalı V.D.: 466 053 3864

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 Küçükcekmece/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.(*)	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, Droppler, EKG, Exercise Test applications, and ensures that the ultrasonography waves come to the device screen more clearly and uninterruptedly.
Basic UDI-DI(*)	KAF G31 — 8682079003KAFG319T KAF G31-1 — 868207900KAFG31-1N4 KAF G31-2 — 868207900KAFG31-2N6 KAF G31-3 — 868207900KAFG31-3N8
Product Classification / Classification Rule(*)	Class 1

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

GMDN Code(*)	15321		
EMDN Code (*After activation)	A108002		
Conformity Assessment Procedure(*) **(Additions executed in the product evaluation are marked)**	☒	ANNEX-IV (Annex II & III)	Declaration of conformity
	☐	ANNEX-IX (CHAPTER I & III)	Quality management system
	☐	ANNEX-IX (PART II)	Technical Documentation Mod.
	☐	ANNEX-X	Type Examination
	☐	ANNEX-XI (PART A)	Production Quality Assurance
	☐	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 Mh. 221 Sk. No:3A Rota Office
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