



CERTIFICATION

# Certificate



**EC UYGUNLUK BEYANI**  
(EC Declaration of Conformity)

KURULUŞ / COMPANY

**KAF GRUP SAĞLIK HİZMETLERİ İNŞAAT SANAYİ VE TİC. LTD. ŞTİ.**

ADRES / ADDRESS

**ATAKENT MAH. 221 SK. NO:3A ROTA OFFICE A BLOK D.83 K.ÇEKMECE / İSTANBUL / TURKEY**

ÜRETİM ADRES / PRODUCTION ADDRESS

**HADIMKÖY MAH. DENİZKIZI SK. NO:4/5 ARNAVUTKÖY / İSTANBUL / TURKEY**

That the following described product in our delivered version complies with appropriate basic safety and health requirements based on 528/2012/EU BIOSIDAL DIRECTIVES on its design and type, as brought into circulation by us. In Case of alteration of the product, not agreed upon by us, this declaration will lose its validity.

PRODUCT DESCRIPTION/ ÜRÜN TANIMI

: ONEHAND ALCOHOL BASED HAND AND  
SKIN ANTISEPTIC LIQUID&GEL

PRODUCT COMMERCIAL BRAND / MARKA

: WANCARE

APPLICABLE EC DIRECTIVES /

UYGULANAN YÖNETMELİKLER

: 528/2012/EU BIOSIDAL DIRECTIVES

APPLICABLE HARMONISED STANDARDS

UYGULANAN STANDARTLAR

: TS EN 13727+A2 – TS EN 14348 - TS EN 13624 -  
TS EN 14476+A2 - TS EN 12791+A1

PRODUCT TYPE / ÜRÜN TİPLERİ

: KAF G59-1, KAF G59-2, KAF G59-3, KAF G59-4,

KAF G59-5, KAF G59-6, KAF G59-7, KAF G59-8, KAF G59-9, KAF G59-10, KAF G59-11, KAF G59-12,

KAF G59-13, KAF G59-14, KAF G59-15, KAF G59-16, KAF G59-17, KAF G59-18, KAF G59-19,

KAF G59-20, KAF G50, KAF G100, KAF G250, KAF G500, KAF G1

TEST REPORT NO / TEST RAPOR NO

: 211555-01/07, 211554-00/09,  
211726-00/06, 220349-00/06

CERTIFICATE NUMBER : 30042020CE0388-2022

CERTIFICATE ISSUE DATE : 12.04.2022

CERTIFICATE VALIDITY DATE : 11.04.2023

FİRMA KAŞE İMZA / COMPANY STAMP SIGN



Bu sertifika, Asist certification'ın belgelendirme şartlarına uyulması ve her yıl yapılacak gözetim denetimlerinin başarılı bir şekilde tamamlanması durumunda, ilk yayın tarihinden itibaren 3 yıl geçerlidir. Bu sertifikanın mülkiyeti ASİST Sertifikasyon Ltd.Şti'ye aittir. İstenildiğinde iadesi zorunludur. Sertifikanın geçerlilik durumu [www.asistekalite.net](http://www.asistekalite.net) adresinden kontrol edilebilir. Asist Sertifikasyon Ltd.Şti. İnciliplınar Mh. İnciliplınar İş Merkezi Kat:3 No:302 Şehitkamil/GAZİANTEP • [www.asistekalite.net](http://www.asistekalite.net) / [info@asistekalite.net](mailto:info@asistekalite.net)





**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](http://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

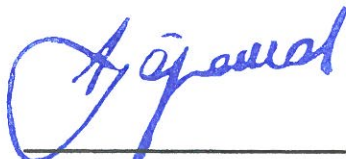
## ISO 9001:2015

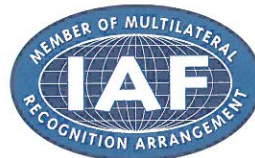
PRODUCTION AND SALES OF STERILE AND NON-STERILE MEDICAL DEVICES AND CONSUMABLES  
(BODY CLEANER, HAND CLEANING WIPES, HAIR RESTRAINT ETC)

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





# Sertifika

**ISO 13485 : 2016**

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

**Merkez: Atakent Mah. 221. Sk. Rota Office A Blok No: 3 A İç Kapı No: 83  
Küçükçekmece/İstanbul/TÜRKİYE  
Van Üretim ve Depo Adresi: Bardakçı Mah. Teknokent Sok. No: 3  
Tuşba / Van/TÜRKİYE**

*Bu sertifika yukarıdaki kuruluşa ait tıbbi cihazlar kalite yönetim sisteminin (EN ISO 13485:2016) aşağıdaki kapsam çerçevesinde PCA Sertifikasyon tarafından onaylandığını göstermekte olup, sertifikanın geçerliliği kuruluşun yıllık gözetim denetimlerinden geçmesine ve uluslararası akreditasyon kuralları gereğince ilgili yönetim sisteminin şartlarını devam ettirmesine bağlıdır.*

## KAPSAM

*Tıbbi cihaz yüzey dezenfektanları, yüksek düzey tıbbi cihaz dezenfektanları, steril kayganlaştırıcı jel, elektrod, elektro cerrahi kalem tipi ve cımbız tipi forcepsler, elektrot tip cerrahi kalem, scalpel ultrasonik cerrahi sistem cihazı ve problemleri ve kablo tasarımı, imalatı ve satışı*

### GRUP KODU

A - B - D - E (M01-M11- MDS7006-MDS7001)

<b>Sertifika No</b>	: TC-75264
<b>Tescil Tarihi</b>	: 24.03.2020
<b>Yeniden Basım Tarihi</b>	: 29.03.2022
<b>Geçerlilik Tarihi</b>	: 23.03.2023
<b>Belge Periyodu</b>	: 3 Yıl (Tescil Tarihinden İtibaren)
<b>Hariç Tutma</b>	: 7.5.3 / 7.5.4 / 7.5.9.2 / 7.5.10 / 8.3.4



**PCA Sertifikasyon Onayı**

PCA Sertifikasyon Hizmetleri Limited Şirketi  
Orta Mah. Ordu Sk. İzparkı 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





# 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  
Van Manufacturing and storage address: Bardakçı Mah. Teknokent Sok. No: 3  
Tuşba / Van/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

*Design manufacturing and sales of medical instrument surface disinfectants, high-level disinfectants for medical instruments, sterile lubricant gel, electrode, electrosurgical pen type and tweezers type forceps, scalpel ultrasonic surgical system device, probes and cable*

### GROUP CODE

A - B - D - E (M01-M11-MDS7006-MDS7001)

**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** : 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





# 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





# Sertifika

**ISO 13485 : 2016**

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

**Merkez: Atakent Mah. 221. Sk. Rota Office A Blok No: 3 A İç Kapı No: 83  
Küçükçekmece/İstanbul/TÜRKİYE  
İstanbul Üretim Adresi: Hadımköy Mahallesi Deniz Kızı Sok. No: 4 / 5  
Arnavutköy / İstanbul/TÜRKİYE**

*Bu sertifika yukarıdaki kuruluşa ait tıbbi cihazlar kalite yönetim sisteminin (EN ISO 13485:2016) aşağıdaki kapsam çerçevesinde PCA Sertifikasyon tarafından onaylandığını göstermekte olup, sertifikanın geçerliliği kuruluşun yıllık gözetim denetimlerinden geçmesine ve uluslararası akreditasyon kuralları gereğince ilgili yönetim sisteminin şartlarını devam ettirmesine bağlıdır.*

## KAPSAM

*Bariyer kremli kese, bone, inkontinans vücut bakımı ve perine mendilleri, vücut ve perine bölgesi temizleme mendilleri, ateller, tespitleyiciler/flaster bantlar ve tüp sabitleyiciler, ultrason ekg jeli, eeg pastası, alkol içermeyen köpük el dezenfektanı, ağız bakım swabı, ağız bakım seti swabı, alkali, nötralizan ve enzim içeren solüsyon, sedye örtüsü imalatı ve satışı*

### GRUP KODU

A

**Sertifika No** : TC-75264  
**Tescil Tarihi** : 24.03.2020  
**Yeniden Basım Tarihi** : 29.03.2022  
**Geçerlilik Tarihi** : 23.03.2023  
**Belge Periyodu** : 3 Yıl (Tescil Tarihinden İtibaren)  
**Hariç Tutma** : 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 Sertifikasyon Onayı**

PCA Sertifikasyon Hizmetleri Limited Şirketi  
Orta Mah. Ordu Sk. İşpark 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

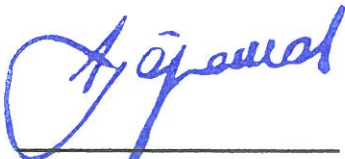
## ISO 14001:2015

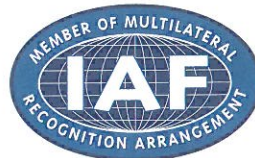
PRODUCTION AND SALES OF STERILE AND NON-STERILE MEDICAL DEVICES AND CONSUMABLES  
(BODY CLEANER, HAND CLEANING WIPES, HAIR RESTRAINT ETC)

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](http://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



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

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



  
General Manager



# Safety Data Sheet

Prepared According Regulation on Registration, Evaluation, Authorization and Restriction of Chemicals  
(Official Gazette No. 23.06.2017- 30105).

**WANCARE**

**WANCARE ALCOHOL BASED HAND AND SKIN ANTISEPTIC**

Date of Issue: 23.03.2020

Revision Date: -

Version No: 1.0

## 1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKIN

- **INFORMATIONS ABOUT THE PRODUCT:** Disinfectant  
**PRODUCT NAME:** WANCARE ALCOHOL BASED HAND AND SKIN ANTISEPTIC
- **NAME AND ADDRESS OF MANUFACTURER**  
**COMPANY NAME:** KAF GRUP SAĞLIK HİZMETLERİ  
**ADDRESS:** Atakent Mah. 221 Sk. No:3/A Rota Office A Blok Kat:14 D:82-83  
K.ÇEKMECE / İSTANBUL  
**TEL:** +90 212 213 21 65 / +90 212 471 4 200  
**FAX:** 90 312 212 67 03  
**E-mail:** info@kafgrup.com  
**Web:** www.kafgrup.com
- **WHO GAVE INFORMATION ABOUT SECURITY:** Ceyhun KURUÇ
- **EMERGENCY TELEPHONE NUMBER:** In case of poisoning, call the National Poison Information Centre (UZEM) number **114**.  
**EMERGENCY FIRST AID CENTRE:**112  
**FIRE DEPARTMENT:**110

## 2. HAZARDS IDENTIFICATION

### 2.1 Classification of Substance and Mixtures

#### Classification

Flam. Liquid 2-H225

Eye Dam.2-H319

Bhot Single Mark.3- H336

**Zeynep DİLEK**  
Sertifika No: 01.85.05



# Safety Data Sheet

Prepared According Regulation on Registration, Evaluation, Authorization and Restriction of Chemicals  
(Official Gazette No. 23.06.2017- 30105).

**WANCARE**

## WANCARE ALCOHOL BASED HAND AND SKIN ANTISEPTIC

Date of Issue: 23.03.2020

Revision Date: -

Version No: 1.0

### 2.2 Label Elements:

#### Special Marking of Certain Mixtures:

Labeling according to T.C. 28848/2013

#### Pictograms:



**GHS07**



**GHS02**

**Signal Word:** Warning

#### Hazard Statements:

H225: Highly flammable liquid and vapour

H319: Causes serious eye irritation.

H336: May cause drowsiness or dizziness.

#### Precautionary Statements:

P210: Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.

P233: Keep container tightly closed.

P240: Ground/bond container and receiving equipment.

P241: Use explosion-proof electrical/ventilating/lighting/.../equipment.

P242: Use only non-sparking tools.

P243: Take precautionary measures against static discharge.

P305 + P351 + P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

P501: Dispose of contents and container in accordance with local regulations.

### 2.3 Other Hazards

It does not contain any components evaluated as PBT and vPvB.

**Zeynep DİLEK**  
Sertifika No: 01.85.05



# Safety Data Sheet

Prepared According Regulation on Registration, Evaluation, Authorization and Restriction of Chemicals  
(Official Gazette No. 23.06.2017- 30105).

**WANCARE**

**WANCARE ALCOHOL BASED HAND AND SKIN ANTISEPTIC**

Date of Issue: 23.03.2020

Revision Date: -

Version No: 1.0

## 3. COMPOSITION/INFORMATION ON INGREDIENTS

### 3.1 Substances

Inapplicable.

### 3.2 Mixtures

Name	EC NO	CAS NO	Content %	Classification (SEA Regulations)
Ethanol	200-578-6	64-17-5	<80%	Flam. Liquid 2 - H225 Eye Dam.2 - H319 Bhot Single Mark.3 - H336
Glycerin	200-289-5	56-81-5	%1 < C < 2%	Unclassified.

**Note:** The full text of the H-codes is given in Section 16.

### About Regulation

The latest data are from T.C and A.B. given in accordance with the regulations

## 4. FIRST AID MEASURES

**General Recommendation:** Move the exposed person to fresh air immediately. If any discomfort continues, consult a doctor.

**Inhalation:** Move the exposed person to fresh air immediately. Provide rest, warmth and fresh air. When breathing difficulties occur, oxygen can be given to the exposed person by properly trained personnel. If any discomfort continues, consult a doctor.

**Zeynep DİLEK**  
Sertifika No: 01.85.05



# Safety Data Sheet

Prepared According Regulation on Registration, Evaluation, Authorization and Restriction of Chemicals  
(Official Gazette No. 23.06.2017- 30105).

**WANCARE**

## WANCARE ALCOHOL BASED HAND AND SKIN ANTISEPTIC

Date of Issue: 23.03.2020

Revision Date: -

Version No: 1.0

**Ingestion:** Do not induce vomiting! Never induce vomiting or drink any liquid to an unconscious person! In case of vomiting, keep the head low so that the stomach does not enter the lungs. Consult a doctor immediately!

**Skin contact:** Flush skin with plenty of water.

**Eye contact:** If there are contact lenses, eyes should be removed before rinsing. Rinse eyes immediately with plenty of water by opening the eyelids. Continue to rinse for at least 15 minutes and call a healthcare professional.

### 4.2 Significant Acute and Delayed Symptoms and Effects

There is no appropriate information.

### 4.3 Indication of any immediate medical attention and special treatment needed

Special treatment is not recommended. Treat according to the symptoms.

## 5. FIRE – FIGHTING MEASURES

### 5.1 Extinguishing Media

**Suitable Extinguishing Media:** Foam, dry chemical powder and sand.

### 5.2 Special Hazards Arising from the Substance or Mixture:

#### Unusual fire and explosion hazards

Vapours can be ignited.

#### Special Hazards

It is a flammable material. Vapours heavier than air may condense on the ground. At elevated temperatures may form flammable mixtures with air. Hazardous flammable gases and vapours may develop in the event of fire.

**Zeynep DİLEK**  
Sertifika No: 01.85.05



# Safety Data Sheet

Prepared According Regulation on Registration, Evaluation, Authorization and Restriction of Chemicals  
(Official Gazette No. 23.06.2017- 30105).

**WANCARE**

## WANCARE ALCOHOL BASED HAND AND SKIN ANTISEPTIC

Date of Issue: 23.03.2020

Revision Date: -

Version No: 1.0

### 5.3 Recommendations for Firefighting Teams

Avoid breathing fire vapours. Cool containers exposed to flames with water until the fire is out.  
Remove container from fire area, if possible without danger.  
Prevent fire-fighting water from running into sewers and watercourses. Build a dike to keep the water under control.

### Protective Equipment

In case of fire, wear self-contained breathing apparatus and full protective suit.

## 6. ACCIDENTAL RELEASE MEASURE

### 6.1 Personal precautions, protective equipment and emergency procedures

Wear protective clothing as shown in section 8 of this safety data sheet.  
Do not smoke, do not use fire, or use any other igniter.  
Avoid inhalation of vapours and contact with skin and eyes. Provide adequate ventilation.  
Pay attention to slippery floors and surfaces in case of spillage.

### 6.2 Environmental Precautions

Do not pour into sewers, soil or waterways. In the event of spills or uncontrolled discharges in waterways, it is necessary to contact the relevant environmental agency or other appropriate control centers IMMEDIATELY.

### 6.3 Methods and Material for Containment and Cleaning Up

DO NOT RELEASE TO SPILLS!

**Zeynep DİLEK**  
Sertifika No: 01.85.05



# Safety Data Sheet

Prepared According Regulation on Registration, Evaluation, Authorization and Restriction of Chemicals  
(Official Gazette No. 23.06.2017- 30105).

**WANCARE**

## WANCARE ALCOHOL BASED HAND AND SKIN ANTISEPTIC

Date of Issue: 23.03.2020

Revision Date: -

Version No: 1.0

**Large spills:** Use necessary protective equipment.

If possible, stop leakage provided there is no danger. Absorb in vermiculite, dry sand or earth and place in boxes. Wash with plenty of water to clean the spillage area.

**Small spills:** Absorb spillage in non-flammable, absorbent material. Transfer to a container for disposal.

### 6.4 Reference To Other Sections

See Section 8 for personal protection.

See Section 11 for additional information on health hazards.

See Section 13 for waste disposal.

## 7. HANDLING AND STORAGE

### 7.1 Handling

#### Precautions For Safe Handling of the Substance / Preparation

Avoid breathing vapours and particles.

### 7.2 Conditions for Safe Storage, Including any Incompatibilities:

It should be stored in well ventilated areas.

**Store away from:** Heat, flames.

**Unsuitable containers:** No data available.

**Packaging Material:** As a container or in surface coatings; Use sheet metal or high density polyethylene (HDPE).

**Zeynep DILEK**  
Seri No: 01.85.05



# Safety Data Sheet

Prepared According Regulation on Registration, Evaluation, Authorization and Restriction of Chemicals  
(Official Gazette No. 23.06.2017- 30105).

**WANCARE**

## WANCARE ALCOHOL BASED HAND AND SKIN ANTISEPTIC

Date of Issue: 23.03.2020

Revision Date: -

Version No: 1.0

Containers made of polyethylene should not be exposed to high temperatures as they may change shape in hot conditions.

### 7.3 Specific End Use(s)

The defined uses of this product are detailed in Section 1.2.

## 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

### 8.1 Control Parameters

Exposure Limits:

Ethanol

WEL

TWA-8 Hours  
100ppm 1920mg / m<sup>3</sup>

### 8.2 Exposure Controls

#### Personal Protective Equipment



#### Process Conditions

Provide eyewash station, safety shower.

#### Technical Measures:

Provide adequate ventilation. Observe occupational exposure limits and reduce the risk of inhaling vapour.

**Zeynep DİLEK**  
Sertifika No: 01.85.05



# Safety Data Sheet

Prepared According Regulation on Registration, Evaluation, Authorization and Restriction of Chemicals  
(Official Gazette No. 23.06.2017- 30105).

**WANCARE**

## WANCARE ALCOHOL BASED HAND AND SKIN ANTISEPTIC

Date of Issue: 23.03.2020

Revision Date: -

Version No: 1.0

### Respiratory Protection:

No special precautions required. In case of discomfort, seek medical advice immediately.

### Protection of Hands:

Suitable gloves for permanent contact:

Material: Butyl-rubber

Usage Time >= 480 minutes

Glove thickness: >= 0.7 mm

Suitable gloves for splash protection:

Material: Nitrile rubber

Usage Time: >= 30 minutes

Glove thickness: >= 0.4 mm

### Eye Protection:

Wear goggles or a face shield.

**Health Precautions:** Wash hands at every shift change and before eating, smoking and using the toilet. Take off immediately all contaminated clothing. In case of contamination of the skin, wash immediately with soap and water. Use a suitable skin cream to prevent the skin from drying. When using, do not eat, drink or smoke.

**Skin Protection:** Protective clothing and boots should be worn. In addition, full protective clothing made of acrylic polyester and rubber or neoprene gloves and shoes should be worn.

**Zeynep DİLEK**  
Serial No: 01.85.05



# Safety Data Sheet

Prepared According Regulation on Registration, Evaluation, Authorization and Restriction of Chemicals  
(Official Gazette No. 23.06.2017- 30105).

**WANCARE**

## WANCARE ALCOHOL BASED HAND AND SKIN ANTISEPTIC

Date of Issue: 23.03.2020

Revision Date: -

Version No: 1.0

### 9. PHYSICAL AND CHEMICAL PROPERTIES

#### 9.1 Information on Basic Physical and Chemical Properties

Appearance	Liquid
Odour	Charecteristic. Perfume Fragrance
Colour	Colourless, transparent
9.2 Other Informations	
Density	0,85 - 1,00 gr /cm3
Flash Point	13° C
Boiling Point	78,4° C
Explotion Danger	No explosive
Viscosity	No data
Solubility ( in Water / Alcohol / Oil )	Soluable in water (in all rate)
Vapour Pressure	No data
Ignition Temperature	425 ° C
pH value 5.5-7.0	5.5-7.0
Melting Point	No data available
Specific Gravity	No information

#### 9.2 Other Information

No information.

### 10. STABILITY AND REACTIVITY

**Zeynep DİLEK**  
Sertifika No: 01.85.05



# Safety Data Sheet

Prepared According Regulation on Registration, Evaluation, Authorization and Restriction of Chemicals  
(Official Gazette No. 23.06.2017- 30105).

**WANCARE**

## WANCARE ALCOHOL BASED HAND AND SKIN ANTISEPTIC

Date of Issue: 23.03.2020

Revision Date: -

Version No: 1.0

- 10.1 Reactivity:** Not expected.
- 10.2 Chemical Stability:** Stable under normal temperature conditions and recommended usage conditions and under stipulated storage conditions.
- 10.3 Possibility of hazardous reactions:** Not expected.
- 10.4 Conditions to avoid:** Avoid exposure to high temperatures or direct sunlight.
- 10.5 Incompatible materials:** No data available.
- 10.6 Hazardous Decomposition Products:** Fire creates: Carbon monoxide (CO). Carbon dioxide (CO<sub>2</sub>).

## 11. TOXICOLOGICAL INFORMATION

### 11.1 Information on toxicological effects

#### Ethanol (CAS: 64-17-5)

ACUTE TOXIC DOSE 1 - LD 50 (oral-rat): 6200 mg / kg

ACUTE TOXIC DOSE 2 - LD 50 (oral - rabbit): 7060 mg / kg

ACUTE TOXIC INTENS. - LC50 (inhalation - rat): 124.7 mg / l / 4h

- **Eye Irritation:** Not available.
- **Skin Sensitization:** No information available.
- **Germ Cell Mutagenicity (in vitro-in vivo):** No information available.
- **Carcinogenicity:** No information available.
- **Reproductive Toxicity-Fertility-Development:** No information available.
- **Inhalation:** Not applicable for normal room temperature. When heated, irritating vapours may be generated.
- **Ingestion:** May cause discomfort if swallowed.
- **Skin Contact:** Not irritating.
- **Eye Contact:** May cause irritation.

**Zeynep DİLEK**  
Seri No: 01.85.05



# Safety Data Sheet

Prepared According Regulation on Registration, Evaluation, Authorization and Restriction of Chemicals  
(Official Gazette No. 23.06.2017- 30105).

**WANCARE**

**WANCARE ALCOHOL BASED HAND AND SKIN ANTISEPTIC**

Date of Issue: 23.03.2020

Revision Date: -

Version No: 1.0

## 12. ECOLOGICAL INFORMATION

### 12.1 Toxicity:

**Ethanol (CAS: 64-17-5)**

LC 50, 96 HOURS, FISH 11000 mg / l

Alburnus alburnus EC50, 48 HOURS,

WATER RICE 3715-6772 mg / l

IC50, 72 HOURS, ALG 9310 mg / l Chlorella pyrenoidosa

**12.2 Persistence and degradability:** No data available.

**12.3 Bioaccumulative Potential:** It is an easily soluble mixture. There are no components that have the potential to accumulate in nature.

**12.4 Mobility in soil:** No data available.

**12.5 Results of PBT and vPvB assessment:** Does not contain any components considered to be PBT and vPvB.

**12.6 Other adverse effects:** None.

## 13. DISPOSAL CONSIDERATIONS

### General Information

When dealing with wastes, safety measures to be taken when dealing with the product itself will be taken into account.

**Zeynep DİLEK**  
Sertifika No: 01.85.05



# Safety Data Sheet

Prepared According Regulation on Registration, Evaluation, Authorization and Restriction of Chemicals  
(Official Gazette No. 23.06.2017- 30105).

**WANCARE**

## WANCARE ALCOHOL BASED HAND AND SKIN ANTISEPTIC

Date of Issue: 23.03.2020

Revision Date: -

Version No: 1.0

### 13.1 Waste Treatment Methods

The disposal of waste must comply with current regulations.

**Additional Information:** Use, storage, transportation and disposal must be done by following legal regulations. Do not pour into surface water and utility water system. Dispose of the waste duly.

## 14. TRANSPORT INFORMATION

14.1 UN Number (ADR / RID / ADN) 1993  
UN No. (IMDG) 1993  
UN No. (ICAO) 1993

14.2 UN Proper Shipping Name:  
FLAMMABLE LIQUID N.O.S.



14.3 Transport Hazard Class(es): 3  
14.4 Packing Group: II  
14.5 Environmental Hazards: Not applicable

**Zeynep DİLEK**  
Sertifika No: 01.85.05

# Safety Data Sheet

Prepared According Regulation on Registration, Evaluation, Authorization and Restriction of Chemicals  
(Official Gazette No. 23.06.2017- 30105).

**WANCARE**

**WANCARE ALCOHOL BASED HAND AND SKIN ANTISEPTIC**

Date of Issue: 23.03.2020

Revision Date: -

Version No: 1.0

## 15. REGULATORY INFORMATION

### 15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture:

#### National Regulations;

- 'Regulation on Preparation of Safety Data Sheets Regarding Hazardous Substances and Mixtures (13.12.2014- Official Gazette No. 29204)
- T.C. Ministry of Environment and Forestry, Regulation on Classification, Packaging and Labeling of Hazardous Substances and Preparations, dated December 26, 2008, No. 27092.
- Regulation on Classification, Labeling and Packaging of Substances and Mixtures, dated 11 December 2013 and numbered 28848.
- Regulation on Health and Safety Measures in Working with Chemical Substances.
- Biocidal Products Regulation No. 27449 (4th Repeating) dated December 31, 2009 Hazardous Waste Control Regulation.
- Regulation on the Use of Personal Protective Equipment in Workplaces.
- Law No. 6331 on Occupational Health and Safety.
- UN ADR, IMDG, IATA LISTS

## 16. OTHER INFORMATION

### Sources of Information

This SDS is organized within the information received from the company that owns the product.

### Revision Information

This SDS has been harmonized with the relevant regulations.

**Zeynep DİLEK**  
Sertifika No: 01.85.05



# Safety Data Sheet

Prepared According Regulation on Registration, Evaluation, Authorization and Restriction of Chemicals  
(Official Gazette No. 23.06.2017- 30105).

**WANCARE**

**WANCARE ALCOHOL BASED HAND AND SKIN ANTISEPTIC**

**Date of Issue: 23.03.2020**

**Revision Date: -**

**Version No: 1.0**

## Prepared By

Name and Surname: Zeynep DİLEK

Contact Informations: zeynep-dilek@outlook.com

Document No: TÜV/11.14.02 - Chemical Evaluation Specialist

New Issue Date -

Preparation Date 23.03.2020

How Many Arrangements Is 1.0

## All of the Hazard Statements

H319: Causes serious eye irritation.

H225: Highly flammable liquid and vapour.

H336: May cause drowsiness or dizziness.

## RESERVATION

Use and application information have been given in the technical prospectus of the product. Details are based on the information that we have today, do not express any assurance about the product quality, and any active case on the subject cannot be represented as justification. This Safety Data Sheet, prepared for WANCARE ALCOHOL BASED HAND AND SKIN ANTISEPTIC product, has been prepared on behalf of KAF GRUP SAĞLIK HİZMETLERİ.

**Zeynep DİLEK**  
Sertifika No: 01.85.05



**T.C. SAĞLIK BAKANLIĞI**  
TÜRKİYE İLAÇ VE  
TIBBİ CİHAZ KURUMU

**BIYOSİDAL ÜRÜN RUHSATNAMESİ**  
(İMAL)

Ruhsat No: 2022/28	Ruhsat Tarihi: 05/04/2022
Ürünün ticari adı / Ürün tipi	WANCARE ONEHAND Alkol Bazlı El Ve Cilt Antiseptiği / 1
Aktif madde/ler isimleri	Ethanol
Aktif madde/ler CAS numaraları	64-17-5
Aktif madde/ler ve oranları	Ethanol %73.0 (h/h)
Hedef canlı/canlılar	<i>S. aureus</i> ; <i>P. aeruginosa</i> ; <i>E. coli</i> ; <i>E. hirae</i> ; <i>C. albicans</i> ; <i>Poliovirus Type 1</i> ; <i>Adenovirus Type 5</i> ; <i>Murine norovirus</i> ; <i>Vaccinia virus Ankara</i> ; <i>M. avium</i> ; <i>M. terrae</i>
Fiziki hâli (Toz, Briket, Granül vb.)	Sıvı
Uygulama dozu	1,4 ml (Medikal Alan)
Ambalaj miktarı/miktarları	20 ml, 50 ml, 100 ml, 125 ml, 250 ml, 300 ml, 400 ml, 500 ml, 700 ml, 750 ml, 800 ml, 1 L, 4 L, 5 L, 10 L, 20 L, 25 L, 30 L, 50 L, 1000 L
Antidotu	Ürünün özel bir antidotu yoktur.
Zararlılık ve Önlem ibareleri	H225, H319; P210, P240, P241, P243, P280, P303+P361+P353, P305+P351+P338, P337+P313, P370+P378, P403+P235, P501
Raf ömrü	2 (İki) Yıl
Ruhsat sahibinin adı ve adresi	KAF GRUP SAĞ. HİZ. İNŞ. SAN. VE TİC. LTD. ŞTİ. Atakent Mah. 221 Sok. Rota Office A Blok No:3A D:82-83 Küçükçekmece İSTANBUL
Fabrika veya imalathanenin adresi	KAF GRUP SAĞ. HİZ. İNŞ. SAN. VE TİC. LTD. ŞTİ. Hadımköy Mah. Deniz Kızı Sok. No:4/5 Arnavutköy/İSTANBUL
Ruhsatın geçerli olduğu süre	05/04/2024
Veriliş tarihi ve nedeni	05/04/2022, İlk Üretim İzni

31/12/2009 tarihli ve 27449 sayılı (4. mükerrer) Resmî Gazete’de yayımlanan Biyosidal Ürünler Yönetmeliği’nin 14’üncü maddesi uyarınca yukarıda adı geçen biyosidal ürünün imaline ve kullanılmasına müsaade edilmiştir.

  
Doç. Dr. Tolga KARAKAN  
Kurum Başkanı

Not: Stabilite testleri tamamlandığında uygun bulunması halinde ruhsat geçerlilik süresi uzatılacaktır.





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

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

# CERTIFICATE of FREE SALES

Certificate No: 2022/4842316/1/25

Date of Issue: 07/07/2022

This is to certify that below product comply with the “By-law on Biocidal Products” of Turkey has been registered and is allowed to be sold in conformity with the laws in Turkey.

## PRODUCT DETAILS

**Product Name:** WANCARE ONEHAND Alkol Bazlı El Ve Cilt Antiseptiđi

**Product Export Name:** WANCARE ONEHAND Alcohol Based Hand and Skin Antiseptic

**Registration Date and Number:** 05/04/2022 - 2022/28

**Active Substance(s) Name, Ratio(s) and CAS No:** Ethanol; %73.0 (h/h); 64-17-5

**Product Type:** 1

**Reason for issuing the certificate:** Export

**License Holder/Adress:** KAF GRUP SAĐLIK HİZMETLERİ İNŞAAT SAN. VE TİC. LTD. ŞTİ.  
Atakent Mah. 221. Sk. No:3A Rota Office A Blok Kat:14 D:82-83

K.Çekmece / İSTANBUL

**Manufacturing Company/Adress:** KAF GRUP SAĐLIK HİZMETLERİ İNŞAAT SAN. VE TİC. LTD. ŞTİ.  
Hadımköy Mah. Deniz Kızı Sok. No:4/5 Arnavutköy/İSTANBUL

*This certificate is valid for 1 year from the date of issue.*



Yücel DENER  
Head of Cosmetic Department





