

**SAFETY DATA SHEET**
**Antibacterial, Antifungusidal and Antiviral Hair Wash Cap  
 Antibacterial, Antifungusidal and Antiviral Wash Gloves**

Commission Regulation (EU) No 2015/830 of 28 May 2015.

**SECTION 1: Identification of the substance/mixture and of the company/undertaking**
**1.1. Product identifier**

**Product name** Antibacterial, Antifungusidal and Antiviral Hair Wash Cap  
 Antibacterial, Antifungusidal and Antiviral Wash Gloves

**1.2. Relevant identified uses of the substance or mixture and uses advised against**

**Identified uses** Disinfectant wipes

**1.3. Details of the supplier of the safety data sheet**

**Supplier** Kaf Grup Sađ. Hizm. İnş. San ve Tic. Ltd. Şti.  
 Atakent Mahallesi 221 Sk. No:3A Rota Office A Blok Kat:14 D:82-83, 34200  
 Küçükçekmece / İSTANBUL, Turkey  
 www.kafgrup.com  
 Tel: 90 0 212 471 4 200

**Contact person** info@kafgrup.com

**1.4. Emergency telephone number**

**Emergency telephone** Tel: +90 0 212 471 4 200 (Working hours: 08:00-18:00)

**SECTION 2: Hazards identification**
**2.1. Classification of the substance or mixture**

**Classification (EC 1272/2008)**

**Physical hazards** Not Classified

**Health hazards** Not Classified

**Environmental hazards** Not Classified

**2.2. Label elements**

**Hazard statements** NC Not Classified

**Labelling notes** This product is an article. Therefore, there is no release of the liquid chemical in product.  
 As supplied, this product does not meet the requirements for labelling.

**2.3. Other hazards**

No data available.

**SECTION 3: Composition/information on ingredients**
**3.2. Mixtures**

<b>Chlorhexidin digluconat</b>	<b>&lt;3 %</b>
CAS number: 18472-51-0	EC number: 242-354-0
M factor (Acute) = 10	M factor (Chronic) = 1

**Classification**

Eye Dam. 1 - H318  
 Aquatic Acute 1 - H400  
 Aquatic Chronic 1 - H410

The full text for all hazard statements is displayed in Section 16.

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### SECTION 4: First aid measures

#### 4.1. Description of first aid measures

<b>General information</b>	If in doubt, get medical attention promptly. Show this Safety Data Sheet to the medical personnel.
<b>Inhalation</b>	Due to the physical nature of this product, exposure by this route is unlikely.
<b>Ingestion</b>	Due to the physical nature of this product, it is unlikely that ingestion will occur.
<b>Skin contact</b>	No specific recommendations.
<b>Eye contact</b>	Due to the physical nature of this product, exposure by this route is unlikely. Rinse with water. Get medical attention if any discomfort continues.
<b>Protection of first aiders</b>	Use protective equipment appropriate for surrounding materials.

#### 4.2. Most important symptoms and effects, both acute and delayed

<b>General information</b>	The severity of the symptoms described will vary dependent on the concentration and the length of exposure.
<b>Inhalation</b>	Due to the physical nature of this product, exposure by this route is unlikely.
<b>Ingestion</b>	Due to the physical nature of this product, exposure by this route is unlikely.
<b>Skin contact</b>	No adverse effects known.
<b>Eye contact</b>	Due to the physical nature of this product, exposure by this route is unlikely. IF IN EYES: Redness. May cause temporary eye irritation.

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

<b>Notes for the doctor</b>	Treat symptomatically.
<b>Specific treatments</b>	No special treatment required.

### SECTION 5: Firefighting measures

#### 5.1. Extinguishing media

<b>Suitable extinguishing media</b>	The product is not flammable. Extinguish with foam, carbon dioxide, dry powder or water fog. Use fire-extinguishing media suitable for the surrounding fire.
<b>Unsuitable extinguishing media</b>	Do not use water jet as an extinguisher, as this will spread the fire.

#### 5.2. Special hazards arising from the substance or mixture

<b>Hazardous combustion products</b>	Thermal decomposition or combustion products may include the following substances: Harmful gases or vapours.
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#### 5.3. Advice for firefighters

<b>Protective actions during firefighting</b>	Avoid breathing fire gases or vapours. Evacuate area. Cool containers exposed to flames with water until well after the fire is out. Control run-off water by containing and keeping it out of sewers and watercourses. If risk of water pollution occurs, notify appropriate authorities.
<b>Special protective equipment for firefighters</b>	Wear positive-pressure self-contained breathing apparatus (SCBA) and appropriate protective clothing. Firefighter's clothing conforming to European standard EN469 (including helmets, protective boots and gloves) will provide a basic level of protection for chemical incidents.

### SECTION 6: Accidental release measures

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

<b>Personal precautions</b>	For personal protection, see Section 8. No action shall be taken without appropriate training or involving any personal risk.
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### 6.2. Environmental precautions

**Environmental precautions** Avoid discharge into drains or watercourses or onto the ground.

### 6.3. Methods and material for containment and cleaning up

**Methods for cleaning up** Reuse or recycle products wherever possible. Collect spillage. Flush contaminated area with plenty of water. Wash thoroughly after dealing with a spillage. Dispose of contents/container in accordance with national regulations.

### 6.4. Reference to other sections

**Reference to other sections** For personal protection, see Section 8. For waste disposal, see Section 13.

## SECTION 7: Handling and storage

### 7.1. Precautions for safe handling

**Usage precautions** Keep out of the reach of children. Read and follow manufacturer's recommendations. Wear protective clothing as described in Section 8 of this safety data sheet. Keep away from food, drink and animal feeding stuffs. Avoid contact with eyes.

**Advice on general occupational hygiene** Wash hands thoroughly after handling.

### 7.2. Conditions for safe storage, including any incompatibilities

**Storage precautions** Store away from incompatible materials (see Section 10). Store in tightly-closed, original container in a dry and cool place. Protect from sunlight.

### 7.3. Specific end use(s)

**Specific end use(s)** The identified uses for this product are detailed in Section 1.2.

## SECTION 8: Exposure controls/Personal protection

### 8.1. Control parameters

#### **Occupational exposure limits**

No exposure limits known for ingredient(s).

### 8.2. Exposure controls

**Appropriate engineering controls** No specific ventilation requirements.

**Eye/face protection** No specific eye protection required during normal use.

**Hand protection** No specific requirements are anticipated under normal conditions of use.

**Hygiene measures** Wash hands thoroughly after handling. Do not eat, drink or smoke when using this product. Wash contaminated clothing before reuse.

**Respiratory protection** No specific recommendations.

**Environmental exposure controls** Not regarded as dangerous for the environment.

## SECTION 9: Physical and chemical properties

### 9.1. Information on basic physical and chemical properties

**Appearance** Solid.

**Colour** Various colours.

**Odour** Characteristic.

**Odour threshold** No information available.

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Commission Regulation (EU) No 2015/830 of 28 May 2015.

pH	Not relevant.
Melting point	No information available.
Initial boiling point and range	No information available.
Flash point	No information available.
Flammability (solid, gas)	No information available.
Upper/lower flammability or explosive limits	No information available.
Vapour pressure	No information available.
Vapour density	No information available.
Relative density	No information available.
Solubility(ies)	Insoluble in water.
Partition coefficient	No information available.
Auto-ignition temperature	No information available.
Decomposition Temperature	No information available.
Viscosity	No information available.
Explosive properties	No information available.
Oxidising properties	No information available.
<b><u>9.2. Other information</u></b>	
Other information	No information required.

### SECTION 10: Stability and reactivity

#### 10.1. Reactivity

**Reactivity** See the other subsections of this section for further details.

#### 10.2. Chemical stability

**Stability** Stable at normal ambient temperatures and when used as recommended. Stable under the prescribed storage conditions.

#### 10.3. Possibility of hazardous reactions

**Possibility of hazardous reactions** No potentially hazardous reactions known.

#### 10.4. Conditions to avoid

**Conditions to avoid** There are no known conditions that are likely to result in a hazardous situation.

#### 10.5. Incompatible materials

**Materials to avoid** Strong alkalis. Strong oxidising agents.

#### 10.6. Hazardous decomposition products

**Hazardous decomposition products** Does not decompose when used and stored as recommended. Thermal decomposition or combustion products may include the following substances: Harmful gases or vapours.

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### SECTION 11: Toxicological information

#### 11.1. Information on toxicological effects

##### Acute toxicity - oral

Notes (oral LD<sub>50</sub>) Based on available data the classification criteria are not met.

##### Acute toxicity - dermal

Notes (dermal LD<sub>50</sub>) Based on available data the classification criteria are not met.

##### Acute toxicity - inhalation

Notes (inhalation LC<sub>50</sub>) Based on available data the classification criteria are not met.

##### Skin corrosion/irritation

Skin corrosion/irritation Based on available data the classification criteria are not met.

##### Serious eye damage/irritation

Serious eye damage/irritation Based on available data the classification criteria are not met.

##### Respiratory sensitisation

Respiratory sensitisation Based on available data the classification criteria are not met.

##### Skin sensitisation

Skin sensitisation Based on available data the classification criteria are not met.

##### Germ cell mutagenicity

Genotoxicity - in vitro Based on available data the classification criteria are not met.

##### Carcinogenicity

Carcinogenicity Based on available data the classification criteria are not met.

##### Reproductive toxicity

Summary Based on available data the classification criteria are not met.

##### Specific target organ toxicity - single exposure

STOT - single exposure Not classified as a specific target organ toxicant after a single exposure.

##### Specific target organ toxicity - repeated exposure

STOT - repeated exposure Not classified as a specific target organ toxicant after repeated exposure.

##### Aspiration hazard

Aspiration hazard Based on available data the classification criteria are not met.

#### Toxicological information on ingredients.

##### Chlorhexidin digluconat

##### Acute toxicity - oral

Notes (oral LD<sub>50</sub>) LD<sub>50</sub> >2000 mg/kg/day, Oral, Rat

### SECTION 12: Ecological information

##### Ecotoxicity

Not regarded as dangerous for the environment. However, large or frequent spills may have hazardous effects on the environment.

#### 12.1. Toxicity

##### Toxicity

Based on available data the classification criteria are not met.  
 No specific test data are available.

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### Ecological information on ingredients.

#### Chlorhexidin digluconat

##### Acute aquatic toxicity

LE(C) <sub>50</sub>	0.01 < L(E)C <sub>50</sub> ≤ 0.1
M factor (Acute)	10
Acute toxicity - fish	LC <sub>50</sub> , 96 hour: 2.08 mg/l, Brachydanio rerio (Zebra Fish)
Acute toxicity - aquatic invertebrates	EC <sub>50</sub> , 48 hour: 0.087 mg/l, Daphnia magna
Acute toxicity - aquatic plants	EC <sub>50</sub> , 72 hour: 0.081 mg/l, Freshwater algae

##### Chronic aquatic toxicity

M factor (Chronic)	1
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#### 12.2. Persistence and degradability

**Persistence and degradability** The degradability of the product is not known.

#### 12.3. Bioaccumulative potential

**Bioaccumulative potential** No data available on bioaccumulation. No potential for bioaccumulation.

**Partition coefficient** No information available.

#### 12.4. Mobility in soil

**Mobility** Not considered mobile.

#### 12.5. Results of PBT and vPvB assessment

**Results of PBT and vPvB assessment** This product does not contain any substances classified as PBT or vPvB.

#### 12.6. Other adverse effects

**Other adverse effects** None known.

### SECTION 13: Disposal considerations

#### 13.1. Waste treatment methods

**General information** The generation of waste should be minimised or avoided wherever possible. Reuse or recycle products wherever possible. This material and its container must be disposed of in a safe way.

**Disposal methods** Dispose of waste to licensed waste disposal site in accordance with the requirements of the local Waste Disposal Authority.

### SECTION 14: Transport information

**General** The product is not covered by international regulations on the transport of dangerous goods (IMDG, IATA, ADR/RID).

#### 14.1. UN number

Not applicable.

#### 14.2. UN proper shipping name

Not applicable.

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### 14.3. Transport hazard class(es)

No transport warning sign required.

### 14.4. Packing group

Not applicable.

### 14.5. Environmental hazards

Environmentally hazardous substance/marine pollutant

No.

### 14.6. Special precautions for user

Not applicable.

### 14.7. Transport in bulk according to Annex II of MARPOL and the IBC Code

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code Not applicable.

## SECTION 15: Regulatory information

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

#### EU legislation

Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) (as amended).

Commission Regulation (EU) No 2015/830 of 28 May 2015.

Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures (as amended).

Regulation No 528/2012 concerning the making available on the market and use of biocidal products.

Regulation (EC) No 648/2004 of the European Parliament and of the Council of 31 March 2004 on detergents (as amended).

#### Guidance

Workplace Exposure Limits EH40.

#### Restrictions (Annex XVII Regulation 1907/2006)

No specific restrictions on use are known for this product.

#### Seveso Directive - Control of major accident hazards

Not applicable. Not relevant.

### 15.2. Chemical safety assessment

No chemical safety assessment has been carried out.

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### SECTION 16: Other information

<b>Abbreviations and acronyms used in the safety data sheet</b>	<p>ADR: European Agreement concerning the International Carriage of Dangerous Goods by Road.          ADN: European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways.          RID: European Agreement concerning the International Carriage of Dangerous Goods by Rail.          IATA: International Air Transport Association.          ICAO: Technical Instructions for the Safe Transport of Dangerous Goods by Air.          IMDG: International Maritime Dangerous Goods.          CAS: Chemical Abstracts Service.          ATE: Acute Toxicity Estimate.          LC<sub>50</sub>: Lethal Concentration to 50 % of a test population.          LD<sub>50</sub>: Lethal Dose to 50% of a test population (Median Lethal Dose).          EC<sub>50</sub>: 50% of maximal Effective Concentration.          PBT: Persistent, Bioaccumulative and Toxic substance.          vPvB: Very Persistent and Very Bioaccumulative.</p>
<b>Key literature references and sources for data</b>	<p>Source: European Chemicals Agency, <a href="http://echa.europa.eu/">http://echa.europa.eu/</a></p>
<b>Revision comments</b>	<p>This is the first issue.</p>
<b>Issued by</b>	<p>Bülent Özdemir / CRAD  <a href="http://www.crad.com.tr">www.crad.com.tr</a> <a href="mailto:gbf@crad.com.tr">gbf@crad.com.tr</a></p>
<b>Note to organizer</b>	<p>This SDS is prepared based on the information and documents received from product owner. CRAD or/and SDS author shall not be responsible for incorrect prepared of SDS and pecuniary loss or intangible damages because of deficient or wrong information and documents which comes from product owner.</p>
<b>Revision date</b>	<p>13/11/2020</p>
<b>Revision</b>	<p>0.1</p>
<b>Supersedes date</b>	<p>13/11/2020</p>
<b>SDS number</b>	<p>10828</p>
<b>Hazard statements in full</b>	<p>H318 Causes serious eye damage.          H400 Very toxic to aquatic life.          H410 Very toxic to aquatic life with long lasting effects.</p>

This information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process. Such information is, to the best of the company's knowledge and belief, accurate and reliable as of the date indicated. However, no warranty, guarantee or representation is made to its accuracy, reliability or completeness. It is the user's responsibility to satisfy himself as to the suitability of such information for his own particular use.





### DECLARATION OF CONFORMITY

#### MANUFACTURER:

Kaf Grup Sağlık Hizmetleri İnşaat Sanayi ve Tic. Ltd. Şti.

Address: Atakent Mh. 221.Sk. No:3A Rota Office K.Çekmece / İstanbul - Turkey

Tel: 00 90 212 471 42 00 Fax: 00 90 212 471 42 01

**Product Name:** Antibacterial and Antifungusidal Body Cleansing Wipes  
Antibacterial and Antifungusidal Perineal Area Cleansing Wipes  
Antibacterial and Antifungusidal Wash Gloves  
Antibacterial and Antifungusidal Hair Wash Cap

**Brand Name:** WANCARE

**Product Code:** KAF G09, KAF G10, KAF G11 / KAF G12, KAF G13, KAF G14 / KAF G03 / KAF G04

**Classification:** Class 1

We herewith declare that the above mentioned products meet the transposition into national law, the provisions of the following EC Council Directives and Standards. All supporting documentations are retained under the premises of the manufacturer. Kaf Grup Sağlık Hizmetleri İnşaat Sanayi ve Tic. Ltd. Şti. is exclusively responsible for Declaration of Conformity.

#### DIRECTIVES

Medical Device Directive: COUNCIL DIRECTIVE 93/42/EEC of 14 JUNE 1993 concerning medical device (MDD 93/42/EEC)

Standard Applied: All applicable harmonized Standard (publish in the Official Journal of the European Communities)

**Declaration Date:** 21.08.2019

**Signature:**

**Name:** Gökmen AYTİN

**Position:** General Manager

KAF GRUP SAĞLIK HİZMETLERİ  
İNŞAAT SANAYİ VE TİC. LTD. ŞTİ.  
Atakent Mh. 221. Sk. No:3A Rota Office  
A Blok D.83 K.Çekmece / İSTANBUL  
Tel: 0212 471 42 00 Fax: 0212 471 42 01  
Halkalı V.D.: 486 053 3864



# CERTIFICATE

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

MERKEZ ADRESİ: ATAKENT MAH. 221. SOK. ROTA OFFICE A BLOK NO:3A D:82-83  
KÜÇÜKÇEKMECE / İSTANBUL / TÜRKİYE  
FABRİKA ADRESİ: HADIMKÖY MAH. DENİZ KIZI SOK. NO:4/5  
ARNAVUTKÖY / İSTANBUL / TÜRKİYE

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

### ISO 9001:2015

*The Quality Management System is applicable to:  
Kalite Yönetim Sistemi:*

PRODUCTION AND SALES OF STERILE AND NON-STERILE MEDICAL DEVICES,  
CONSUMABLES (BODY CLEANING, HAND CLEANING WIPES, HAIR CAP, ULTRASOUND  
GEL, ADHESIVE REMOVER SPRAY)

STERİL VE NON-STERİL TIBBİ CİHAZLARIN, SARF MALZEMELERİN  
(VÜCUT TEMİZLEME, EL TEMİZLEME MENDİLİ, SAÇ BONESİ, ULTRASON JELİ,  
YAPIŞKAN SÖKÜCÜ SPREY) ÜRETİMİ VE SATIŞI

Certificate Number: QMS-0109832  
Belge Numarası: QMS-0109832

Initial Certification Date: 24.02.2023  
İlk Belgelendirme Tarihi: 24.02.2023

Certification Period: 3 Years  
Belgelendirme Periyodu: 3 Yıl

Certificate Validity Date: 23.02.2024  
Belge Geçerlilik Tarihi: 23.02.2024

IQR Sertifikasyon Onayı



ACCREDITED  
Management Systems  
Certification Body

MSCB-135

IQR ULUSLARARASI BELGELENDİRME HİZMETLERİ LTD.ŞTİ.

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

Tel.: +90.224.266 00 16 Faks: +90.224.249 41 13 www.iqrcert.com e-posta: info@iqrcert.com



# 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	: 21.03.2023
Geçerlilik Tarihi	: 23.03.2024
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



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Management  
Systems  
Certification Body

MSCB-103

PCA Sertifikasyon Onayı

PCA Sertifikasyon Hizmetleri Limited Şirketi  
Orta Mah. Ordu Sk. İzpark C Blok No:26/23 Kartal / İSTANBUL  
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www.pca-tr.com info@pca-tr.com



# 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 permeal cloths; body and permeal 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

<b>Certificate No</b>	: TC-75264
<b>Registration Date</b>	: 24.03.2020
<b>Reissue Date</b>	: 21.03.2023
<b>Expiry Date</b>	: 23.03.2024
<b>Certificate Period</b>	: 3 Years (From the date of registration)
<b>Exclusion</b>	: 4.1.5 / 4.1.6 / 7.3 / 7.5.3 / 7.5.4 / 7.5.9.2 / 7.5.10 / 8.3.4



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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  
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# 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

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### 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 probraları ve kablo tasarımı, imalatı ve satışı

#### GRUP KODU

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

Sertifika No	: TC-75264
Tescil Tarihi	: 24.03.2020
Yeniden Basım Tarihi	: 21.03.2023
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Harç Tutma	: 7.5.3 / 7.5.4 / 7.5.9.2 / 7.5.10 / 8.3.4



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Certification Body

MSCB-103

PCA Sertifikasyon Onayı

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

# 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

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)

<b>Certificate No</b>	: TC-75264
<b>Registration Date</b>	: 24.03.2020
<b>Reissue Date</b>	: 21.03.2023
<b>Expiry Date</b>	: 23.03.2024
<b>Certificate Period</b>	: 3 Years (From the date of registration)
<b>Exclusion</b>	: 7.5.3 / 7.5.4 / 7.5.9.2 / 7.5.10 / 8.3.4



ACCREDITED

Management  
Systems  
Certification Body

MSCB-103

PCA Certification Approval

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