

WANCARE

ULTRASOUND ECG gel

USAGE

Ensures clearer and uninterrupted transmission of ultrasonographic waves by disconnecting the air between the skin and the prob during any and all Ultrasonography, Doppler ECG or effort test.

PROPERTIES

pH balanced between 5,00 - 7,00.
No toxic effect. Not irritate the skin.
Water soluble. Easy to clean.
Not contain formaldehyde and salt. Odorless.



COMPOSITION

Deionized water, Carbormer, TriEthanol Amine, MonoPropylene Glycol, Benzyl Alcohol, Methylchloroisothiazolinone

STORAGE CONDITIONS

Please store under 35°C keep away from direct sunlight, store in a cool and dry place.



SIZE	REF NO
250ML	KAF G31-2
500ML	KAF G31-1
1LT	KAF G31
5LT	KAF G31-3



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	Awann GmbH. Industriestrasse 43-45, 50389 Wesseling GERMANY HRB: 106071 info@awann.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, Doppler, EKG, Exercise Test applications, and ensures that the ultrasonography waves come to the device screen more clearly and uninterruptedly.	
Basic UDI-DI(*)	Catalog No	Basic UDI code
	KAFG 31	868207900KAFG31DG
	KAFG 31-1	868256095KAFG31-1WD
	KAFG 31-2	868256095KAFG31-2WF
	KAFG 31-3	868256095KAFG31-3WH
Product Classification / Classification Rule(*)	Class 1 according to Rule 1 and 5 in Annex VIII of the Medical Device Regulation	

GMDN Code(*)	15321		
EMDN Code (*After activation)	Z11040185		
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 10993-1:2020	EN ISO 10993-11:2018
	EN ISO 10993-23:2021	EN ISO 15223-1:2021	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 : 21.12.2023

Effective Date (if applicable) :

Signatory : Gökmen AYTİN

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
A Blok D:14 Küçükçekmece İSTANBUL
Tel: 0212 471 42 00 Fax: 0212 471 42 01
Etilkaf@kaf.com.tr 485 053 3864



THE REPUBLIC OF TÜRKİYE
MINISTRY OF HEALTH
MEDICINES AND MEDICAL DEVICES AGENCY OF TÜRKİYE

Certificate No: 385009

Date of Issue : 28 November 2023

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 Türkiye 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 3 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>.

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 : 28 November 2023

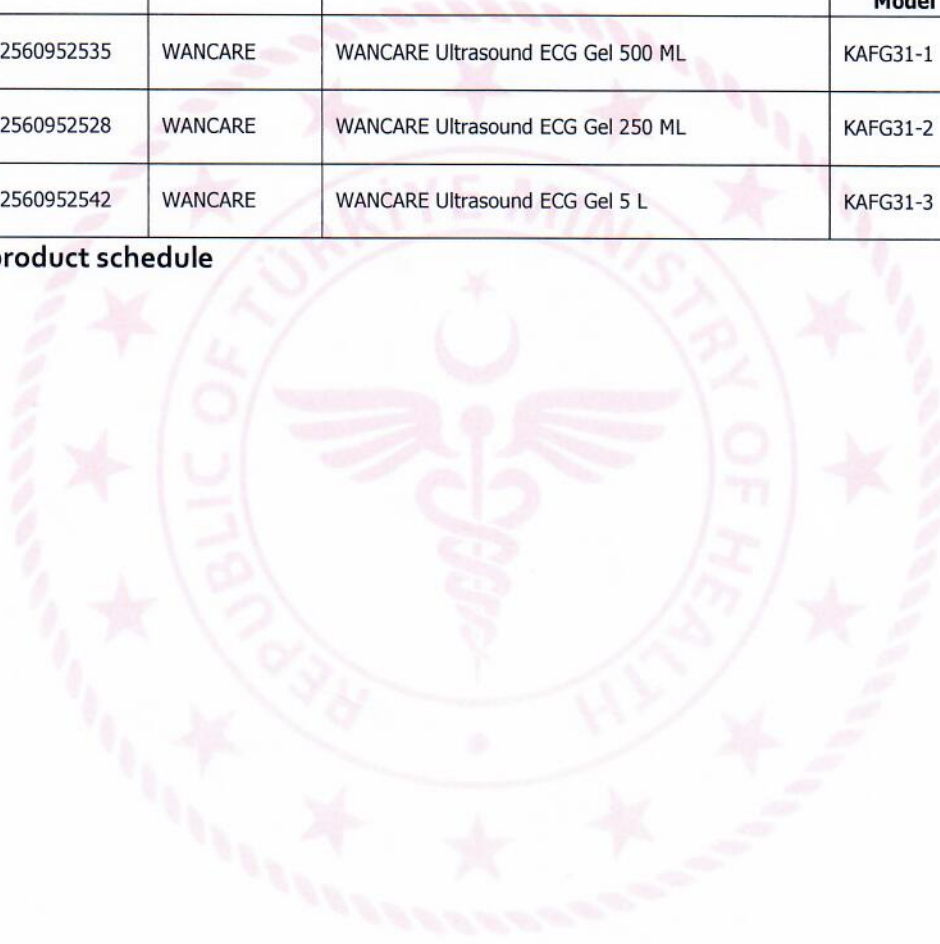
PRODUCT SCHEDULE

Basic UDI-DI: 868256095TD13MA

Related EU Certificate(s) (if any): - ; -

#	UDI-DI	Brand	Label Name	Reference No / Version / Model	GMDN Code
1	8682560952535	WANCARE	WANCARE Ultrasound ECG Gel 500 ML	KAFG31-1	15321
2	8682560952528	WANCARE	WANCARE Ultrasound ECG Gel 250 ML	KAFG31-2	15321
3	8682560952542	WANCARE	WANCARE Ultrasound ECG Gel 5 L	KAFG31-3	15321

End of product schedule





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

Certificate No: 166417

Date of Issue : 29 September 2021

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.

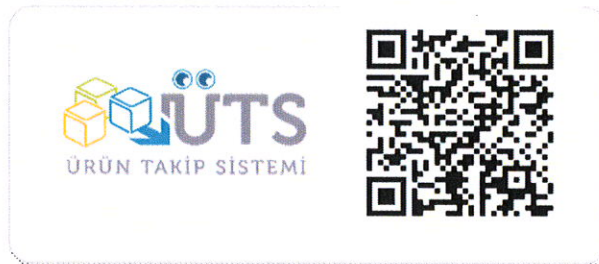
This certificate is issued to be given to the relevant competent authorities of other countries and is valid for 36 months from the date of issue.

Yours sincerely,

Omer Faruk KURU
Head of Medical Devices

Registration and Coordination Department

This certificate consists of 2 page/s and 1 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>.

Address: Söğütözü 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 : 29 September 2021

PRODUCT SCHEDULE

#	Barkod	Brand	Label Name	Reference No / Version / Model	GMDN Code
1	8682079003551	WANCARE	WANCARE ULTRASOUND - ECG GEL 1000ml	-	15321

End of product schedule.

