

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

<b>Manufacturer Name(*)</b>	KAF GRUP SAĞLIK HİZMETLERİ İNŞ. SAN. VE TİC. LTD. ŞTİ		
<b>Manufacturer Address(*)</b>	Atakent Mah. 221 Sk. No:3A Rota Office A Blok Kat:14 D:83 Küçükçekmece/Istanbul/Turkey		
<b>Agency Company (In Poland)</b>	Meringer Sp. z o.o. Kalisz 62-800 Dobrzecka street 95/8a Vat No. PL 618-20-95-132		
<b>Manufacturer Individual Identity No.</b>			
<b>If the product is produced by someone else by the manufacturer, the Manufacturer's Name and Address (* if any)</b>			
<b>Name of the product(*)</b>	WANCARE ULTRASOUND ECG GEL		
<b>Catalog/Reference No. (*)</b>	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	
<b>Purpose of usage(*)</b>	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.		
<b>Basic UDI-DI(*)</b>	8682079003KAFG319T		
<b>Product Classification / Classification Rule(*)</b>	Class 1		
<b>GMDN Code(*)</b>	15321		
<b>EMDN Code (*After activation)</b>	A108002		
<b>Conformity Assessment Procedure(*)</b>	<input checked="" type="checkbox"/>	ANNEX-IV (Annex II & III)	Declaration of conformity
	<input type="checkbox"/>	ANNEX-IX (CHAPTER I & III)	Quality management system

## 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/Turkey

(Additions executed in the product evaluation are marked)	<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	<b>Harmonized Standards</b>		
	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 : 20.01.2022

Effective Date (if applicable) :

Signatory : Gökmen Aytin

Mission : General Manager

[Signature and Seal/Stamp]

KAF GRUP SAĞLIK HİZMETLERİ  
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