

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)			
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(*)	8682079003KAFG319T		
Product Classification / Classification Rule(*)	Class 1		
GMDN Code(*)	15321		
EMDN Code (*After activation)	A108002		
Conformity Assessment Procedure(*)	<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

(Additions executed in the product evaluation are marked)	<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 10993-5: 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 : 06.12.2021

Effective Date (if applicable) :

Signatory : **Gökmèn Aytin**

Mission : **General Manager**

[Signature and Seal/Stamp]

KAF GRUP SAĞLIK HİZMETLERİ
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