KAF GRUP SAĞLIK HİZMETLERİ İNŞ. SAN. TİC. LTD. ŞTİ
Atakent Mahallesi 221 Sk. No:3A Rota Office A Blok Kat:14 D:83
Küçükçekmece/Istanbul/Turkey

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 Küçükcekmece/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

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GMDN Code(*)	15321		
EMDN Code (*After activation)	Z11040185		
Conformity Assessment Procedure(*) **(Additions executed in the product evaluation are marked)**	☒	ANNEX-IV (Annex II & III)	Declaration of conformity
	☐	ANNEX-IX (CHAPTER I & III)	Quality management system
	☐	ANNEX-IX (PART II)	Technical Documentation Mod.
	☐	ANNEX-X	Type Examination
	☐	ANNEX-XI (PART A)	Production Quality Assurance
	☐	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
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