KAF GRUP
SAĞLIK HİZMETLERİ

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)	
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(*)	☒ 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

Digitally signed by Chitic Vlad
Date: 2023.10.02 16:17:27 EEST
Reason: MoldSign Signature
Location: Moldova

Copia conforme cu originalul
Chitic Vlad

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(Additions executed in the product evaluation are marked)	☐	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 10993-5: 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.

Copia corespunde originalului
Cristi Vlad

Signature Date and Place : 06.12.2021

Effective Date (if applicable) :

Signatory : Gökmen Aytin

Mission : General Manager

[Signature and Seal/Stamp]

KAF GRUP SAĞLIK HİZMETLERİ İNŞAAT SANAYİ VE TİC. LTD. ŞTİ.
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