

# KAF GRUP

SAĞLIK HİZMETLERİ

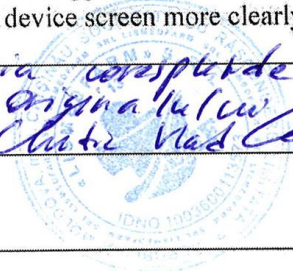
**KAF GRUP SAĞLIK HİZMETLERİ İNŞ. SAN. TİC. LTD. ŞTİ**  
Atakent Mahallesi 221 Sk. No:3A Rota Office A Blok Kat:14 D:83  
Küçükçekmece/Istanbul/Turkey

## EU Medical Device Regulation 2017/745

### Declaration of Conformity

|   |  |  |
|---|--|--|
| <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<br>Küçükçekmece/Istanbul/Turkey  |  |
| <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, Dropler, 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 |
|   | <input type="checkbox"/>   | ANNEX-IX (PART II) Technical Documentation Mod.      |
|   | <input type="checkbox"/>   | ANNEX-X Type Examination                             |

*Copie coraspunde  
originalului  
Clăușă Vlad*



# 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

|   |                             |                       |                              |
|---|-----------------------------|-----------------------|------------------------------|
| (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 | <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.

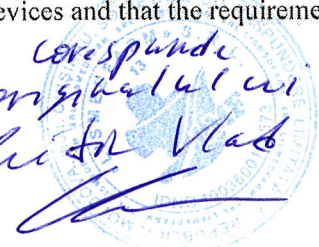
Signature Date and Place : 06.12.2021

Effective Date (if applicable) :

Signatory : **Gökmen Aytin**

Mission : **General Manager**

[Signature and Seal/Stamp]

*Copie correspondance original en turc*  
*Clive Aytin*  
  
KAF GRUP SAĞLIK HİZMETLERİ  
İNŞAAT SANAYİ VE TİC. LTD. ŞTİ.  
Atakent Mh. 221 Sk. No:3A Rota Office  
A Blok D:83 K.Çekmece / İST. / TÜRKİYE  
Tel: 0212 471 42 00 Fax: 0212 471 42 01  
Halkalı V.D: 486 052 3864