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
Authorized European Representative	Anxietas Ug. Industriestrasse 43, 50389 Berzdorf Köln/GERMANY Köln HRB: 106071 info@anxietas.de
Name of the product	WANCARE ONESEPT ENZYM ENZYMATIC SOLUTION FOR MEDICAL INSTRUMENT WASHERS WANCARE ONESEPT ENZYM ENZYMATIC SOLUTION FOR MEDICAL INSTRUMENT AND ENDOSCOPES
Catalog/Reference No.	Name Of The Product / Catalog No Wancare Onesept Enzym Enzymatic Solution For Medical Instrument Washers — KAF G32 Wancare Onesept Enzym Enzymatic Solution For Medical Instrument And Endoscopes — KAF G40
Purpose of usage	*Wancare Onesept Enzymatic* solution for medical instrument washing machines is an alkaline concentrated instrument cleaning detergent containing a triple enzyme complex developed for use in automatic washing machines. *Wancare Enzymatic Solution For Medical Instrument And Endoscopes* is suitable for endoscope washing machines, ultrasonic washing machines and manual use.
Basic UDI-DI	KAF G32 868207900KAFG32DJ KAF G40 868207900KAFG40DH
Product Classification / Classification Rule	Class 1
GMDN Code	63385
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.

Digitally signed by Chitic Ecaterina
Date: 2023.01.14 14:31:06 EET
Reason: MoldSign Signature
Location: Moldova

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)	☐	ANNEX-X	Type Examination
	☐	ANNEX-XI (PART A)	Production Quality Assurance
	☐	ANNEX-XI (PART B)	Product Verification

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

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 : 18.07.2022

Effective Date (if applicable) :

Signatory : Gökmen AYTİN

Mission : General Manager

[Signature and Seal/Stamp]

KAF GRUP SAĞLIK HİZMETLERİ
İNŞAAT SANAYİ VE TİC.LTD.ŞTİ.
Atakent Mh. 221 Sk. No:3A Rota Office
A Blok D:83 K.Çekmece / İSTANBUL
Tel: 0212 471 42 00 Fax: 0212 471 42 01
Halkalı V.D.: 486 053 3864