

#### 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 Küçükçekmece/Istanbul/Turkey		
<b>Authorized European Representative</b>	Anxietas Ug. Industriestrasse 43, 50389 Berzdorf Köln/GERMANY Köln HRB: 106071 info@anxietas.de		
<b>Name of the product(*)</b>	WANCARE ONESURFACE C Concentrated Floor and Surface Disinfectant		
<b>Catalog/Reference No. (*)</b>	<i>Product Name</i>		<i>Catalog No.</i>
	ONESURFACE C Concentrated Floor and Surface Disinfectant		KAF G22
<b>Basic UDI-DI(*)</b>	<i>Catalog No.</i>	<i>Basic UDI-DI</i>	
	KAF G22	868207900KAFG22DF	
<b>Product Classification / Classification Rule(*)</b>	Class 1 / Rule 1		
<b>Conformity Assessment Procedure(*)</b>  (Additions executed in the product evaluation are marked)	<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
	<input type="checkbox"/>	ANNEX-XI (PART A)	Production Quality Assurance
	<input type="checkbox"/>	ANNEX-XI (PART B)	Product Verification
<b>Other EU Legislation / Common Specifications / Harmonized Standards to which the product complies</b>	<b>Harmonized Standards</b>		
	EN ISO 13485:2016	TS EN 13727+A2	TS EN 14348
	TS EN 13624	TS EN 14476+A2	TS EN 12791+A1

(\*) 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)

# 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

**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** : 14.06.2023

**Effective Date (if applicable)** : 14.06.2024

**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 Küçükçekmece / İSTANBUL  
Tel: 0212 471 42 00 Faks: 0212 471 42 01  
Tic. Sic. No.: 405 053 3864