

#### KAF GRUP SAĞLIK HİZMETLERİ İNŞ. SAN. TİC. LTD. ŞTİ

Atakent Mahallesi 221 Sk. No:3A Rota Office A Blok Kat 14 D:83 Küçükçekmece/İstanbul/Türkiye

# **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(*)	Barrier Cream Incontinence Wipes				
	Barrier Cream Incontinence Perineal Cloths				
	Wash Gloves With Barrier Cream				
Catalog/Reference No.(*)	Product Name	Catalog No			
	Barrier Cream Incontinence Wipes (8 pcs)	KAF G49			
	Barrier Cream Incontinence Wipes (12 pcs)	KAF G01			
	Barrier Cream Incontinence Wipes (25 pcs)	KAF G08			
	Barrier Cream Incontinence Wipes (50 pcs)	KAF G07			
	Barrier Cream Incontinence Wipes (100 pcs)	KAF G50			
	Barrier Cream Incontinence Perineal Cloths (8 pcs)	KAF G51			
	Barrier Cream Incontinence Perineal Cloths (12 pcs)	KAF G06			
	Barrier Cream Incontinence Perineal Cloths (25 pcs)	KAF G02			



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		ce/istanbul/Turk				
	Barrier Cream Incontinence Perineal Cloths (50 pcs)		KAF G05			
	Barrier Cream Inco	ntinence Perineal				
	Cloths (100 pcs)		KAF G52			
	Wash Gloves With	Barrier Cream	KAF G16			
Purpose of usage(*)	ONECARE Barrier Creamy Incontinence Wipes and Perineal Cloths are used to create a barrier layer to protect the incontinence-related skin of patients with special needs, such as those with reduced mobility, bedridden and intensive care patients, by cleaning urine and feces contact from external factors. It prevents skin damage that may occur due to pH change and irritation in the body.  ONECARE Wash Gloves with Barrier Cream are used to create a barrier layer to protect the incontinence-related skin of patients with special needs, such as those with reduced mobility, bedridden and intensive care patients, by cleaning urine and feces contact from external factors. It prevents skin damage that may occur due to pH change and irritation in the body.					
Basic UDI-DI(*)  Product Classification	Catalog No         Basic UDI-DI           KAF G49         868256095KAFG49KJ           KAF G01         868256095KAFG01JN           KAF G08         868256095KAFG08K4           KAF G07         868256095KAFG07K2           KAF G50         868256095KAFG50K3           KAF G51         868256095KAFG51K5           KAF G06         868256095KAFG06JY           KAF G02         868256095KAFG02JQ           KAF G05         868256095KAFG05JW           KAF G52         868256095KAFG52K7           KAF G16         868207900KAFG16DL					
/ Classification Rule(*)	Class 1					
GMDN Code(*)	46205					
EMDN Code (*After activation)	Z120113					
Conformity Assessment	ANNEX-IX (CHAPTER I &			claration of conformity nality management system		
Procedure(*)	ANNEX-IX (PART II) Tec		Technical Documen Type Examination	hnical Documentation Mod.		



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(Additions executed in		ANNEX-XI (PART	(A)	Production Quality Assurance	
the product evaluation are marked)		ANNEX-XI (PART	(B)	Product Ve	
Notified Body Name and Number (**)					
EU Certificate No and Description Start/Effective date (**)			2		
Other EU Legislation / Common Specifications / Harmonized Standards to which the product complies	Harmonized Standards				
	E	N ISO 13485:2016	14,000,000	10993-5: 09	EN ISO 10993-1: 2020
	EN	ISO 15223-1: 2021	EN ISO 1 20	0993-10: 21	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: 05.08.2022

Effective Date (if applicable):

Signatory

Gökmen Aytin

Mission

General Manager

[Signature and Seal/Stamp]