

KAFGRUP

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/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 Küçükçekmece/İstanbul/Turkey		
Manufacturer Individual Identity No.			
If the product is produced by someone else by the manufacturer, the Manufacturer's Name and Address (* if any)			
Authorized European Representative	Awann GmbH, Industriestrasse 43-45, 50389 Wesseling GERMANY HRB: 106071 info@awann.de		
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	

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	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																								
	Barrier Cream Incontinence Perineal Cloths (50 pcs)	KAF G05																								
	Barrier Cream Incontinence Perineal Cloths (100 pcs)	KAF G52																								
	Wash Gloves With Barrier Cream	KAF G16																								
Purpose of usage(*)	<p>ONECARE Barrier Creamy Incontinence Pad Wipe and Perineal Pad 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.</p> <p>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.</p>																									
Basic UDI-DI(*)	<table><tr><th>Catalog No</th><th>Basic UDI-DI</th></tr><tr><td>KAF G49</td><td>868256095KAFG49KJ</td></tr><tr><td>KAF G01</td><td>868256095KAFG01JN</td></tr><tr><td>KAF G08</td><td>868256095KAFG08K4</td></tr><tr><td>KAF G07</td><td>868256095KAFG07K2</td></tr><tr><td>KAF G50</td><td>868256095KAFG50K3</td></tr><tr><td>KAF G51</td><td>868256095KAFG51K5</td></tr><tr><td>KAF G06</td><td>868256095KAFG06JY</td></tr><tr><td>KAF G02</td><td>868256095KAFG02JQ</td></tr><tr><td>KAF G05</td><td>868256095KAFG05JW</td></tr><tr><td>KAF G52</td><td>868256095KAFG52K7</td></tr><tr><td>KAF G16</td><td>868207900KAFG16DL</td></tr></table>	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	
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Product Classification / Classification Rule(*)	Class 1																									
GMDN Code(*)	46205																									

EMDN Code (*After activation)	T99		
Conformity Assessment Procedure(*) (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
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: 2021	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 : 18.12.2024

Effective Date (if applicable) :

Signatory : Gökmen Aytin

Mission : General Manager

[Signature and Seal/Stamp]

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