

KAFGRUP SAĞLIK HİZMETLERİ	EC DECLARATION			
	Document No	Issue Date	Revision No	Revision Date
	TD. 04.51	10.06.2019	06	05.03.2024



EC DECLARATION OF CONFORMITY

Medical Devices Directive 93/42/EEC

Company Name	:	KAF GRUP SAĞLIK HİZMETLERİ İNŞ. SAN. TİC. LTD. ŞTİ
Authorized Person / Title	:	Gökmen Aytin / General Manager
Head Office Address	:	Atakent Mahallesi 221 Sk. No:3A Rota Office A Blok Kat:14 D:83 Küçükçekmece/İstanbul/Türkiye
Production Address	:	Bardakçı Mah. Teknokent Sk. No:3 Tuşba/VAN/Türkiye
Phone Number	:	0212 471 42 00
Website	:	www.kafgrup.com
E-Mail	:	info@kafgrup.com
Brand Information	:	WANCARE

as, the models and GMDN Codes of our Onesurface Alcohol-Free Fast Acting Spray Disinfectant For Medical Equipments, Onespray Alcohol-Based Fast Acting Spray Disinfectant For Medical Equipments, Onesurface Wipes Alcohol- Free Fast Acting Disinfectant Wipes For Medical Devices, Onespray Wipes Alcohol-Based Fast Acting Disinfectant Wipes For Medical Devieces products specified in the TD.04.22 **Product Model and GMDN Code Table** and below;

REFERENCE CODE	PRODUCT NAME	ACTIVE SUBSTANCE	VOLUME	GMDN CODE	CLASS
KAF G20-1	Onespray Alcohol-Based Fast Acting Spray Disinfectant For Medical Equipments	Ethyl Alcohol, Isopropyl Alcohol, QAC	750 ml	47631	Ila
KAF G20-2	Onespray Alcohol-Based Fast Acting Spray Disinfectant For Medical Equipments	Ethyl Alcohol, Isopropyl Alcohol, QAC	1 L	47631	Ila
KAF G20-3	Onespray Alcohol-Based Fast Acting Spray Disinfectant For Medical Equipments	Ethyl Alcohol, Isopropyl Alcohol, QAC	5 L	47631	Ila
KAF G21-1	Onesurface Alcohol-Free Fast Acting Spray Disinfectant For	Hydrogen Peroxide+QAC	750 ml	47631	Ila

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	Medical Equipments				
KAF G21-2	Onesurface Alcohol-Free Fast Acting Spray Disinfectant For Medical Equipments	Hydrogen Peroxide+QAC	1 L	47631	Ila
KAF G21-3	Onesurface Alcohol-Free Fast Acting Spray Disinfectant For Medical Equipments	Hydrogen Peroxide+QAC	5 L	47631	Ila
KAF G35-1	Onespray Wipes Alcohol-Based Fast Acting Disinfectant Wipes For Medical Devices	Ethyl Alcohol, Isopropyl Alcohol, QAC	100 Pcs	58077	Ila
KAF G35-2	Onespray Wipes Alcohol-Based Fast Acting Disinfectant Wipes For Medical Devices	Ethyl Alcohol, Isopropyl Alcohol, QAC	150 Pcs	58077	Ila
KAF G35-3	Onespray Wipes Alcohol-Based Fast Acting Disinfectant Wipes For Medical Devices	Ethyl Alcohol, Isopropyl Alcohol, QAC	200 Pcs	58077	Ila
KAF G36-1	Onesurface Wipes Alcohol-Free Fast Acting Disinfectant Wipes For Medical Devices	Hydrogen Peroxide+QAC	100 Pcs	58077	Ila
KAF G36-2	Onesurface Wipes Alcohol-Free Fast Acting Disinfectant Wipes For Medical Devices	Hydrogen Peroxide+QAC	150 Pcs	58077	Ila
KAF G36-3	Onesurface Wipes Alcohol-Free Fast Acting Disinfectant Wipes For Medical Devices	Hydrogen Peroxide+QAC	200 Pcs	58077	Ila

EN ISO 13485:2016/A11:2021	EN 62366-1:2015/A1:2020	EN ISO 20417:2021
EN 14476:2013+A2:2019	EN 14885:2022/AC:2023	EN 13624:2021
EN ISO 14971:2019/A11:2021	EN ISO 15223-1:2021	ASTM F1980-16
EN 13727:2012+A2:2015	TS 10340:1992	EN 17126: 2018
EN 2871-2:2010	EN 16615:2015	EN 14348:2005
TS 6773:1989	EN 13704:2018	European Pharmacopoeia (Ph. Eur.) 11th Edition

Manufactured to harmonized standards, and we declare that it complies with the provisions of the

Medical Device Directive 93/42/EEC Annex II excluded (4)

Full Quality Assurance Certificate

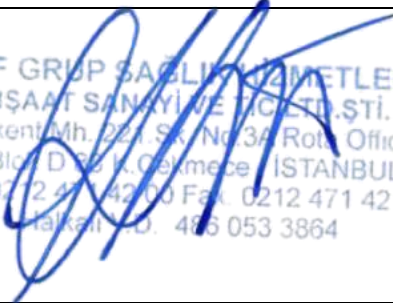
Class Ila

(93/42/EC Annex IX, Rule 15)

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GMND Code	47631- Quaternary (quaternary) ammonium compound device disinfectant/cleaner
GMDN Description	Liquid substance that contains chemical cleaners and quaternary ammonium compounds as primary disinfection agent, used to clean and disinfect medical devices (eg, surgical or dental instruments). To achieve disinfection, the medical device is typically immersed in the agent for a specified period of time or the agent is applied manually to the medical device. This device cannot be reutilized after application.
GMND Code	58077- Medical device cleaning/disinfection wipe
GMDN Description	Pre-treated fabric designed to clean and disinfect the surfaces of medical devices and instruments by wiping for individual patient use. This fabric is impregnated with a solution of detergent(s) and antimicrobial agent(s), and is designed to reduce the amount of soiling and microbial contamination on the surfaces of medical devices and instruments; This product is not designed to be the main form of instrument cleaning and disinfection. It is a disposable device.

Notified Body	:	TÜRK STANDARDLARI ENSTİTÜSÜ
Notified Body Address	:	Necatibey Cad. No:112 06100 Bakanlıklar/ANKARA/TÜRKİYE
Notified Body Identity No	:	1783
Certificate No	:	1783-MDD-211
Issue Date of Certificate	:	17.05.2021
Validity Date of Certificate	:	26.05.2024
CE Marking Start Date	:	17.05.2021
Company Declaration Date	:	05.03.2024
Place of Declaration	:	İSTANBUL-TÜRKİYE
Declarant	:	Gökmen Aydin / GENEL MANAGER
Approval	:	 KAF GRUP SAĞLIK HİZMETLERİ İNŞAAT SANAYİ VE TİCARET A.Ş. Atakent Mh. 221. Sk. No:3A/10. Kat Ofis A Blok D:35 K. Çekmece / İSTANBUL Tel: 0212 471 42 00 Faks: 0212 471 42 01 E-posta: info@kafgrup.com.tr