	<b>EC DECLARATION</b>			
	<b>Document No</b>	<b>Issue Date</b>	<b>Revision No</b>	<b>Revision Date</b>
	TD. 04.51	10.06.2019	05	07.04.2023




### EC DECLARATION OF CONFORMITY

#### Medical Devices Directive 93/42/EEC

<b>Company Name</b>	:	KAF GRUP SAĞLIK HİZMETLERİ İNŞ. SAN. TİC. LTD. ŞTİ
<b>Authorized Person / Title</b>	:	Gökmen Aytin / General Manager
<b>Head Office Address</b>	:	Atakent Mahallesi 221 Sk. No:3A Rota Office A Blok Kat:14 D:83 Küçükçekmece/İstanbul/Türkiye
<b>Production Address</b>	:	Bardakçı Mah. Teknokent Sk. No:3 Tuşba/VAN/Türkiye
<b>Phone Number</b>	:	0212 471 42 00
<b>Website</b>	:	www.kafgrup.com
<b>E-Mail</b>	:	info@kafgrup.com
<b>Brand Information</b>	:	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.) 10th 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 )**

Authorized European Representative: Awann GmbH,  
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50389 Wesseling  
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[info@awann.de](mailto:info@awann.de)

<b>GMND Code</b>	47631- Quaternary (quaternary) ammonium compound device disinfectant/cleaner
<b>GMDN Description</b>	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.
<b>GMND Code</b>	58077- Medical device cleaning/disinfection wipe
<b>GMDN Description</b>	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.

<b>Notified Body</b>	:	TÜRK STANDARDLARI ENSTİTÜSÜ
<b>Notified Body Address</b>	:	Necatibey Cad. No:112 06100 Bakanlıklar/ANKARA/TÜRKİYE
<b>Notified Body Identity No</b>	:	1783
<b>Certificate No</b>	:	1783-MDD-211
<b>Issue Date of Certificate</b>	:	17.05.2021
<b>Validity Date of Certificate</b>	:	26.05.2024
<b>CE Marking Start Date</b>	:	17.05.2021
<b>Company Declaration Date</b>	:	21.08.2023
<b>Place of Declaration</b>	:	İSTANBUL-TÜRKİYE
<b>Declarant</b>	:	Gökmen Aytin / GENEL MANAGER
<b>Approval</b>	:	 KAF GRUP SAĞLIK HİZMETLERİ İNŞAAT SANAYİ VE TİCARET ŞTİ. Atakent Mh. 221. Sk. No:38 Rota Office A Blok D:02 K:02 Kat:02 İSTANBUL Tel: 0212 471 42 00 Fax: 0212 471 42 01 E-posta: info@kafgrup.com.tr