

	<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	03	26.05.2021



**EC DECLARATION OF CONFORMITY**

**Medical Devices Directive 93/42/EEC**

<b>Company Name</b>	:	KAF GRUP SAĞLIK HİZMETLERİ İNŞ. SAN. ve TİC. LTD. ŞTİ
<b>Authorized Person / Title</b>	:	Gökmen Aytin / General Manager
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<b>Web</b>	:	www.kafgrup.com
<b>Mail</b>	:	info@kafgrup.com
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<b>Brand Information</b>	:	WANCARE

as, the models and GMDN Codes of our OneSurface Alcohol-Free Fast Acting Spray Disinfectant for Medical Equipment, OneSpray Alcohol Based Fast Acting Spray Disinfectant for Medical Equipment, OneSurface Wipes Alcohol Free Fast Acting Disinfectant Wipes for Medical Devices, OneSpray Wipes Alcohol Based Fast Acting Disinfectant Wipes for Medical Devices products specified in the **TD.04.22 Product Model and GMDN Code Table** and below;

Reference Code	Product Code	Active Substance	Volume	GMDN CODE	Class
KAF G20-1	OneSpray Alcohol Based Fast Acting Spray Disinfectant for Medical Equipment	Ethyl Alcohol, Isopropyl Alcohol, QAC	750 ml	47631	IIa
KAF G20-2	OneSpray Alcohol Based Fast Acting Spray Disinfectant for Medical Equipment	Ethyl Alcohol, Isopropyl Alcohol, QAC	1 L	47631	IIa

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KAF G20-3	OneSpray Alcohol Based Fast Acting Spray Disinfectant for Medical Equipment	Ethyl Alcohol, Isopropyl Alcohol, QAC	5 L	47631	IIa
KAF G21-1	OneSurface Alcohol-Free Fast Acting Spray Disinfectant for Medical Equipment	Hydrogen Peroxide +QAC	750 ml	47631	IIa
KAF G21-2	OneSurface Alcohol-Free Fast Acting Spray Disinfectant for Medical Equipment	Hydrogen Peroxide +QAC	1 L	47631	IIa
KAF G21-3	OneSurface Alcohol-Free Fast Acting Spray Disinfectant for Medical Equipment	Hydrogen Peroxide +QAC	5 L	47631	IIa
KAF G35-1	OneSpray Wipes Alcohol Based Fast Acting Disinfectant Wipes for Medical Devices	Ethyl Alcohol, Isopropyl Alcohol, QAC	100 Pcs	58077	IIa
KAF G35-2	OneSpray Wipes Alcohol Based Fast Acting Disinfectant Wipes for Medical Devices	Ethyl Alcohol, Isopropyl Alcohol, QAC	150 Pcs	58077	IIa
KAF G35-3	OneSpray Wipes Alcohol Based Fast Acting Disinfectant Wipes for Medical Devices	Ethyl Alcohol, Isopropyl Alcohol, QAC	200 Pcs	58077	IIa
KAF G36-1	OneSurface Wipes Alcohol Free Fast Acting Disinfectant Wipes for Medical Devices	Hydrogen Peroxide +QAC	100 Pcs	58077	IIa
KAF G36-2	OneSurface Wipes Alcohol Free Fast Acting Disinfectant Wipes for Medical Devices	Hydrogen Peroxide +QAC	150 Pcs	58077	IIa
KAF G36-3	OneSurface Wipes Alcohol Free Fast Acting Disinfectant Wipes for Medical Devices	Hydrogen Peroxide +QAC	200 Pcs	58077	IIa

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EN ISO 13485:2016	EN 62366-1:2015	EN ISO 15223-1:2016	EN 1041:2008+A1:2013
EN ISO 14971: 2012	EN 14885:2018	EN 14476:2013 +A2:2019	EN 16615 :2015
EN 13727:2012+A2:2015	EN 14348: 2005	EN 13624: 2013	TS 6773:1989
EN 2871-2:2010	EN 17126: 2018	European Pharmacopoeia (Ph. Eur.) 9th Edition	Meddev 2.4.1 rev 9
Meddev 2.7.1 rev 4	Meddev 2.12-2 rev 2: 2012	Meddev 2.12-1 rev.8	ASTM F1980-16

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

**Medical Device Directive 93/42/AT Annex II excluding (4)**  
**Full Quality Assurance System**  
**Class IIa**  
**(93/42/AT Annex IX, Rule 15)**

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<b>GMND Kodu</b>	47631- Quarternier (quaternary) ammonium compound device disinfectant/cleaner
<b>GMDN Açıklaması</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 Kodu</b>	58077- Medical device cleaning / disinfection wiping
<b>GMDN Açıklaması</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
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<b>Notified Body Address</b>	:	Necatibey Cad. No:112 06100 Bakanlıklar/ANKARA/ TURKEY
<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>	:	26.05.2021
<b>Place of Declaration</b>	:	İSTANBUL-TURKEY
<b>Declarant</b>	:	Gökmen Aytin / GENERAL MANAGER
<b>Approval</b>	:	<p><b>KAF GRUP SAĞLIK HİZMETLERİ</b> <b>İNŞAAT SANAYİ VE TİC. LTD. ŞTİ.</b> Atakent Mr. 223 Sk. No:3A Road Office A Blok D.83/3 Çekirgece / İSTANBUL Tel: 0212 471 42 00 Fax: 0212 471 42 01 Malkalı Y.D. 486 053 8864</p>