

	EC DECLARATION			
	Document No	Issue Date	Revision No	Revision Date
	TD. 05.51	10.06.2019	04	26.05.2021



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/TURKEY
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Production Address	:	Bardakçı Mah. Teknokent Sk. No:3 Tuşba/VAN
Brand Information	:	WANCARE

as, the models and GMDN Codes of our **High Level Medical Device Disinfectant** products specified in the **TD.05.22 Product Model and GMDN Code Table** and below;

REFEENCE CODE	PRODUCT NAME	ACTIVE SUBSTANCE	VOLUME	GMDN CODE	CLASS
KAF G23	OneSEPT GA High Level Disinfectant for Medical Instruments and Endoscopes	Glutaraldehyde	5 L	47631	IIb
KAF G24	OneSEPT PA High Level Disinfectant for Medical Instruments and Endoscopes	Peracetic acid	5 L	47631	IIb
KAF G25	OneSEPT OPA High Level Disinfectant for Medical Instruments and Endoscopes	Orthophthalaldehyde	5 L	47631	IIb
KAF G26-1	OneSEPT PA POWDER	Peracetic acid	2 KG	47631	IIb

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	High Level Disinfectant for Medical Instruments and Endoscopes				
KAF G26-2	OneSEPT PA POWDER High Level Disinfectant for Medical Instruments and Endoscopes	Peracetic acid	2,5 KG	47631	IIb
KAF G26-3	OneSEPT PA POWDER High Level Disinfectant for Medical Instruments and Endoscopes	Peracetic acid	5 KG	47631	IIb

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 14561:2006
EN 13727:2012+A2:2015	EN 14562:2006	EN 13624: 2013	EN 14563: 2008
EN 14348: 2005	EN 13704: 2018	TS 6773:1989	EN 17126:2018
EN 14651:2005+A1:2007			

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

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

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GMDN Code	47631- Medical Device Disinfectant
GMDN Description	A substance containing chemical substance(s) intended to destroy microorganisms or inhibit their activity on a medical device (eg, surgical or dental instrument) and/or facility surface (disinfectant); it may also contain surfactants / cleaning agents or enzymes (eg protease, lipase, amylase) and may additionally be intended for descaling of equipment. The medical device is intended to be exposed to the substance for a specified period of time to provide disinfection by bathing, wiping and/or in combination with a disinfection system/unit. Available in liquid,

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aerosol, powder or tablet form; It is not supplied in a special wipe, cap, or other contact application carrier.

Notified Body	:	TÜRK STANDARLARI ENSTİTÜSÜ
Notified Body Address	:	Necatibey Cad. No:112 06100 Bakanlıklar/ANKARA/TURKEY
Notified Body Identity No	:	1783
Certificate No	:	1783-MDD-212
Issue Date of Certificate	:	17.05.2021
Validity Date of Certificate	:	26.05.2024
CE Marking Start Date	:	17.05.2021
Company Declaration Date	:	26.05.2021
Place of Declaration	:	İSTANBUL-TURKEY
Declarant	:	Gökmen Aydin / GENERAL MANAGER
Approval	:	<p>KAF GRUP SAĞLIK HİZMETLERİ İNŞAAT SANAYİ VE TİC.LTD.ŞTİ. Atakent Mh. 221 Sk. No:3A Kota Office A Blok D:3 K:Çekirgece /İSTANBUL Tel: 0212 471 42 00 Fax: 0212 471 42 01 Halkın V.D. : 486 053 8864</p>