



**TÜRK STANDARLARI ENSTİTÜSÜ**  
TURKISH STANDARDS INSTITUTION

## Full Quality Assurance Certificate

### Directive 93/42/EEC on Medical devices, Annex II excluding (4)

Notified Body	: Türk Standartları Enstitüsü (TSE) - Necatibey Cad. No:112 Bakanlıklar Ankara Turkey (NB 1783)
Company Name	: KAF GRUP SAĞLIK HİZMETLERİ İNŞ. SAN. VE TİC. LTD. ŞTİ.
Company Address	: ATAKENT MAH. 221. SOK. NO:3A ROTA OFFICE A BLOK KAT 14 D:83 34200 KÜÇÜKÇEKMECE/ İSTANBUL/ TURKEY
Manufacturing Site	: BARDAKÇI MAH. TEKNOKENT SK. NO:3 TUŞBA/ VAN/ TURKEY
Scope	: WANCARE MEDICAL DEVICE SURFACE DISINFECTANTS
GMDN Code	: 47631, 58077
Classification Rule	: Rule 15, Class IIa
Inspection Report Number	: 2205-MDD-174/2020-02
First Issue Date	: 17.05.2021
Validity Date	: 26.05.2024

The manufacturer's quality system is inspected in accordance with Annex II of the Medical Device Directive and the quality system meets the requirements of Medical Device Directive Annex II. The Notified Body has the right to carry out the necessary inspections in accordance with Medical Device Directive Annex II Section 5. For Class III products covered by this certificate, a EC Design Examination Certificate issued in accordance with Medical Device Directive Annex II Section 4 is also required.

**Certificate No: 1783- MDD-211**



**Fırat HACIOĞLU**  
Deputy Director of Directives  
ANKARA Rev00, 17/05/2021

Please check the validity of certificate from TSE's web page "<https://basvuruportal.tse.org.tr/Genel/FirmaArama.aspx?ref=en#open>"

[www.tse.org.tr](http://www.tse.org.tr) / Necatibey Cad. No: 112 Bakanlıklar - ANKARA / +90 312 416 62 00

Bu belge hiçbir suretle tahrif edilemez, kısmen veya okunmasını zorlaştıracak şekilde çoğaltılamaz, kazıntı ve silinti yapılamaz.  
This certificate cannot be altered, partially duplicated or erased for misunderstanding.



# TÜRK STANDARTLARI ENSTİTÜSÜ

TURKISH STANDARDS INSTITUTION

## Full Quality Assurance Certificate Scope Attachment

Directive 93/42/EEC on Medical devices, Annex II excluding (4)

Certificate No: 1783-MDD-211, Rev 00

Brand Name: WANCARE

### Product List

Product Name	Product Reference No	GMDN Code
OneSpray Alcohol Based Fast Acting Spray Disinfectant for Medical Equipment	KAF G20-1	47631
OneSpray Alcohol Based Fast Acting Spray Disinfectant for Medical Equipment	KAF G20-2	47631
OneSpray Alcohol Based Fast Acting Spray Disinfectant for Medical Equipment	KAF G20-3	47631
OneSurface Alcohol-Free Fast Acting Spray Disinfectant for Medical Equipment	KAF G21-1	47631
OneSurface Alcohol-Free Fast Acting Spray Disinfectant for Medical Equipment	KAF G21-2	47631
OneSurface Alcohol-Free Fast Acting Spray Disinfectant for Medical Equipment	KAF G21-3	47631
OneSpray Wipes Alcohol Based Fast Acting Disinfectant Wipes For Medical Devices	KAF G35-1	58077
OneSpray Wipes Alcohol Based Fast Acting Disinfectant Wipes For Medical Devices	KAF G35-2	58077
OneSpray Wipes Alcohol Based Fast Acting Disinfectant Wipes For Medical Devices	KAF G35-3	58077
OneSurface Wipes Alcohol Free Fast Acting Disinfectant Wipes For Medical Devices	KAF G36-1	58077
OneSurface Wipes Alcohol Free Fast Acting Disinfectant Wipes For Medical Devices	KAF G36-2	58077
OneSurface Wipes Alcohol Free Fast Acting Disinfectant Wipes For Medical Devices	KAF G36-3	58077



[www.tse.org.tr](http://www.tse.org.tr) / Necatibey Cad. No: 112 Bakanlıklar - ANKARA / +90 312 416 62 00

Bu belge hiçbir suretle tahrif edilemez, kısmen veya okunmasını zorlaştıracak şekilde çoğaltılamaz, kazıntı ve silinti yapılamaz.  
This certificate cannot be altered, partially duplicated or erased for misunderstanding.



**TÜRK STANDARTLARI ENSTİTÜSÜ**  
TURKISH STANDARDS INSTITUTION

**Full Quality Assurance Certificate Certification History**

**Directive 93/42/EEC on Medical devices, Annex II excluding (4)**

**Certificate No: 1783-MDD-211, Rev 00**

CERTIFICATE HISTORY		
Date	Revision Number	Reason of Revision
17.05.2021	Rev 00	-

