



TÜRK STANDARTLARI 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	: ONEGEL LUBRICANT GEL WITH LIDOCAINE (STERILE)
GMDN Code	: 37717
Classification Rule	: Rule 5 and Rule 13, Class III
Inspection Report Number	: 2203-MDD-173/2020-02
First Issue Date	: 24.05.2021
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-238



Fırat HACIOĞLU
Deputy Director of Directives
ANKARA Rev00, 24/05/2021

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



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Full Quality Assurance Certificate Certification History

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Certificate No: 1783-MDD-238, Rev 00

CERTIFICATE HISTORY		
Date	Revision Number	Reason of Revision
24.05.2021	Rev 00	-





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Full Quality Assurance Certificate Scope Attachment

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

Certificate No: 1783-MDD-238, Rev 00

Brand Name: ONEGEL

Product List

Product Name	Product Reference No	GMDN Code
ONEGEL LUBRICANT GEL WITH LIDOCAINE (STERILE) 6 ml	KAF G27-6	37717
ONEGEL LUBRICANT GEL WITH LIDOCAINE (STERILE) 11 ml	KAF G27-11	37717
ONEGEL LUBRICANT GEL WITH LIDOCAINE (STERILE) 12,5 gr	KAF G27-12,5	37717

