



TÜRK STANDARDLARI ENSTİTÜSÜ
TURKISH STANDARDS INSTITUTION

EC Design-Examination Certificate

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

Notified Body : Türk Standardları 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

Full Quality Assurance Certificate Number : 1783-MDD-238

Above scope has been examined and certified according to the requirements of 93/42 / EC - Medical Device Directive Annex-II Section 4. This certificate is valid with its annexes. It is totally 2 pages, including this page. The products included in the scope mentioned above must also have a certificate of Full Quality Assurance (Annex II excluding Section 4). The Notified Body has the right to carry out the necessary inspections in accordance with Medical Device Directive Annex II Section 5.

Certificate No: 1783-MDD-239



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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EC Design Examination Certificate Annex

Certificate No: 1783-MDD-239, 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

CERTIFICATE HISTORY

Date	Revision Number	Reason of Revision
24.05.2021	Rev 00	-

