

**EC DECLARATION****Document No**

TD. 03.51

**Issue Date**

10.06.2019

**Revision No**

03

**Revision Date**

26.05.2021

**EC DECLARATION OF CONFORMITY****Medical Devices Directive 93/42/EEC**

<b>Company Name</b>	:	KAF GRUP SAĞLIK HİZMETLERİ İNŞ. SAN. TİC. LTD. ŞTİ
<b>Authorized Person / Title</b>	:	Gökmen Aydin / General Manager
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<b>Mail</b>	:	info@kafgrup.com
<b>Production Address</b>	:	Bardakçı Mah. Teknokent Şk. No:3 Tüşba/VAN/ TURKEY
<b>Brand Information</b>	:	ONEGEL

as, the models and GMDN Codes of our **Onegel Lubricat Gel With Lidocaine (Sterile)** products specified in the **TD.03.22 Product Model and GMDN Code Table**;

**Product List**

Reference Code	Product Name	Substance	Volume	GMDN CODE	Class
KAF G27-6	ONEGEL LUBRICANT GEL WITH LIDOCAINE	Lidocaine HCL 2%, Chlorhexidine Gluconate 0,05%, Methyl Hydroxybenzoate, Propyl Hydroxybenzoate, Propylene Glycol, Hydroxyethyl Cellulose, Purified Water.	6 ml	37717	III

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KAF G27-11	ONEGEL LUBRICANT GEL WITH LIDOCAINE	Lidocaine HCL 2%, Chlorhexidine Gluconate 0,05%, Methyl Hydroxybenzoate, Propyl Hydroxybenzoate, Propylene Glycol, Hydroxyethyl Cellulose, Purified Water.	11 ml	37717	III
KAF G27-12,5	ONEGEL LUBRICANT GEL WITH LIDOCAINE	Lidocaine HCL 2%, Chlorhexidine Gluconate 0,05%, Methyl Hydroxybenzoate, Propyl Hydroxybenzoate, Propylene Glycol, Hydroxyethyl Cellulose, Purified Water.	12,5 g	37717	III

EN ISO 13485:2016  
 EN 1041:2008+A1:2013  
 EN ISO 10993-6:2016  
 EN ISO 10993-12:2012  
 EN ISO 14644-3:2019  
 EN ISO 11607-2:2018  
 EN ISO 11137-1:2015  
 EN 868-5:2017  
 ASTM F 1929-15  
 EN 14698-2:2003  
 European Pharmacopoeia (Ph. Eur.)  
 10th Edition  
 Meddev 2.7.1 rev 4

EN ISO 15223-1:2016  
 EN ISO 62366-1:2015  
 EN ISO 10993-10:2013  
 EN ISO 14644-1:2015  
 EN ISO 14644-4:2001  
 EN ISO 11737-1:2018  
 EN ISO 11137-2:2015  
 EN ISO 10993-5:2009  
 ASTM F 88/F88 M  
 EN ISO 7886-1:2018  
 Meddev 2.12-1 rev.8

EN ISO 14971:2019  
 EN ISO 10993-1: 2018  
 EN ISO 10993-3:2014  
 EN ISO 14644-2:2015  
 EN ISO 11607-1:2018  
 EN ISO 11737-2:2009  
 EN 556-1:2001/AC:2006  
 ASTM F 1980-16  
 EN ISO 14698-1:2003  
 USP 43-NF 38  
 Meddev 2.12-2 rev 2



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



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**Medical Device Directive 93/42/EEC Annex II (4)**  
**Full Quality Assurance Certificate**  
**Class III**  
**(93/42/AT Annex IX, Rule 13 ve Rule 5)**

Authorized European Representative: Anxietas Ug,  
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50389 Berzdorf  
Köln/GERMANY  
Köln HRB: 106071  
[info@anxietas.de](mailto:info@anxietas.de)

<b>GMND Code</b>	37717- Transurethral instrument lubricant
<b>GMDN Description</b>	A lubricant designed to facilitate the manipulation of a surgical instrument within the body during endoscopic processes of the urinary canal. This device cannot be reutilized after application.

<b>Notified Body</b>	: TÜRK STANDARTLARI ENSTİTÜSÜ
<b>Notified Body Address</b>	: Necatibey Cad. No:112 06100 Bakanlıklar/ANKARA
<b>Notified Body Identity No</b>	: 1783
<b>Design Certificate No</b>	: 1783-MDD-239
<b>Issue Date of Design Certificate</b>	: 24.05.2021
<b>Validity Date of Design Certificate</b>	: 26.05.2024
<b>Design Inspection Report Number</b>	: 2203-MDD-173/2020-02
<b>Quality Certificate No</b>	: 1783-MDD-238
<b>Issue Date of Quality Certificate</b>	: 24.05.2021
<b>Validity Date of Quality Certificate</b>	: 26.05.2024
<b>Quality Inspection Report Number</b>	: 2203-MDD-173/2020-02
<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>	: KAF GRUP SAĞLIK HİZMETLERİ İNŞAAT SANAYİ VE TİC. LTD. ŞTİ. Atakent Mh/ 227. Sk. No:3A Koba Osk. A Blok D. 83 K. Zekiyeciler/ İSTANBUL Tel: 0212 471 42 00 Fax: 0212 471 42 01 Halkın V.D. 486 053 6864

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