

<b>KAFGRUP</b> SAĞLIK HİZMETLERİ	<b>EC DECLARATION</b>			
	<b>Document No</b>	<b>Issue Date</b>	<b>Revision No</b>	<b>Revision Date</b>
	TD. 03.51	10.06.2019	03	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 Aytin / General Manager
<b>Head Office Address</b>	:	Atakent Mahallesi 221 Sk. No:3A Rota Office A Blok Kat 14 D:83 Küçükçekmece/İstanbul/TURKEY
<b>Phone Number</b>	:	Bardakçı Mah. Teknokent Sk. No:3 Tuşba/VAN
<b>Web</b>	:	+90 212 471 42 00
<b>Mail</b>	:	www.kafgrup.com
<b>Production Address</b>	:	info@kafgrup.com
<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 Aydin / GENERAL MANAGER
<b>Approval</b>	:	<p> KAF GRUP SAĞLIK HİZMETLERİ  İNŞAAT SANAYİ VE TİC. LTD. ŞTİ.  Atakent Mh. 221. Sk. No:3A Kofa Ofisi  A Blok D.83 K.Çekmece / İSTANBUL  Tel: 0212 411 42 00 Fax: 0212 471 42 01  Halkın V.D. 486 053 6864 </p>