

Document No	Issue Date	Revision No	Revision Date
TD. 03.51	10.06.2019	04	23.02.2022

**EC DECLARATION OF CONFORMITY****Medical Devices Directive 93/42/EEC - Medical Devices Directive (93/42/AT)**

Company Name	:	KAF GRUP SAĞLIK HİZMETLERİ İNŞ. SAN. TİC. LTD. ŞTİ
Authorized Person / Title	:	Gökmen Aytin / General Manager
Head Office Address	:	Atakent Mahallesi 221 Sk. No:3A Rota Office A Blok Kat 14 D:83 Küçükçekmece/İstanbul/TURKEY
Production Address	:	Bardakçı Mah. Teknokent Sk. No:3 Tuşba/VAN
Phone Number	:	+90 212 471 42 00
Web	:	www.kafgrup.com
Mail	:	info@kafgrup.com
Brand Information	:	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

EC DECLARATION

Document No	Issue Date	Revision No	Revision Date
TD. 03.51	10.06.2019	04	23.02.2022

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

2017/745/EU Medical Device Regulation

EN ISO 13485:2016
EN 1041:2008+A1:2013
EN ISO 10993-6:2016
EN ISO 10993-12:2021
EN ISO 14644-3:2019
EN ISO 11607-2:2020
EN ISO 11137-1:2015
EN 868-5:2019
ASTM F 1929-15
EN 14698-2:2003
European Pharmacopoeia (Ph. Eur.)
10th Edition
Meddev 2.7.1 rev 2016

EN ISO 15223-1:2021
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.2013

EN ISO 14971:2019
EN ISO 10993-1: 2020
EN ISO 10993-3:2014
EN ISO 14644-2:2015
EN ISO 11607-1:2020
EN ISO 11737-2:2020
EN 556-1:2001/AC:2006
ASTM F 1980-16
EN ISO 14698-1:2003
USP 43-NF 38
Meddev 2.12-2 rev 2:2012

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

Document No	Issue Date	Revision No	Revision Date
TD. 03.51	10.06.2019	04	23.02.2022

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,
Industriestrasse 43,
50389 Berzdorf
Köln/GERMANY
Köln HRB: 106071
info@anxietas.de

GMND Code	37717- Transurethral instrument lubricant
GMDN Description	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.

Notified Body	: TÜRK STANDARTLARI ENSTİTÜSÜ
Notified Body Address	: Necatibey Cad. No:112 06100 Bakanlıklar/ANKARA
Notified Body Identity No	: 1783
Design Certificate No	: 1783-MDD-239
Issue Date of Design Certificate	: 24.05.2021
Validity Date of Design Certificate	: 26.05.2024
Design Inspection Report Number	: 2203-MDD-173/2020-02
Quality Certificate No	: 1783-MDD-238
Issue Date of Quality Certificate	: 24.05.2021
Validity Date of Quality Certificate	: 26.05.2024
Quality Inspection Report Number	: 2203-MDD-173/2020-02
Company Declaration Date	: 23.02.2022
Place of Declaration	: İSTANBUL-TURKEY
Declarant	: Gökmen Aytin / GENERAL MANAGER
Approval	:  KAF GRUP SAĞLIK HİZMETLERİ İNŞAAT SANAYİ VE TİC. LTD. ŞTİ. Atakent Mh. 221. Sk. No: 3A Rofa Office A Blok D: 83 K. Çekmece / İSTANBUL Tel: 0212 471 42 00 Fax: 0212 471 42 01 Halkalı V.D.: 486 053 3864