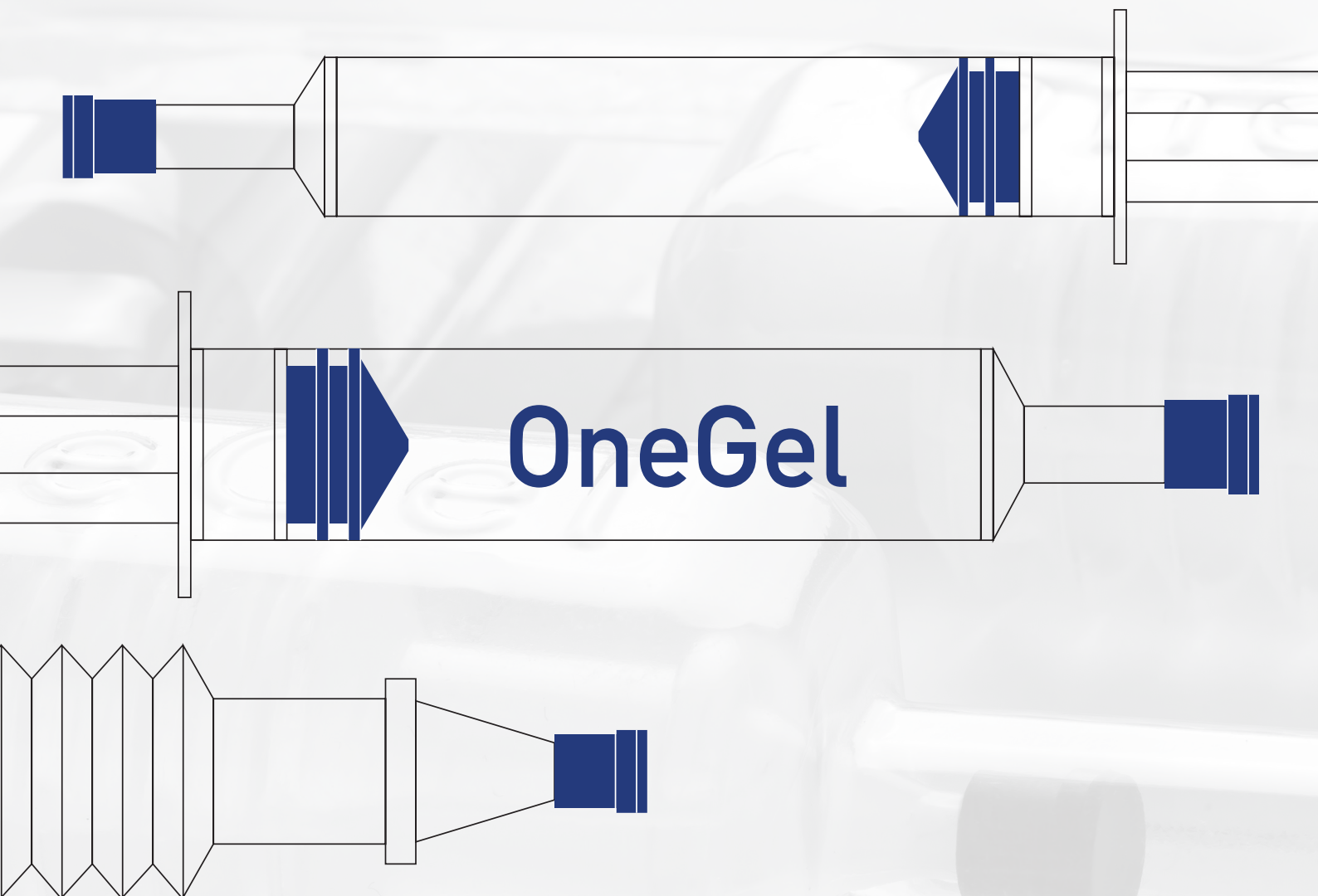




REGISTRUL DE STAT AL DISPOZITIVELOR MEDICALE

Nr	Denumire	Den.comerc.	Model	Nr. catalog	Tara	Producatorul	Reprezentant	Ordin	Data
					turcia		sofra		
DM000368066	GEL LUBRIFIANT UREATRAL CU LIDOCAINĂ	ONEGEL	11 ML	KAF G27-11	Turcia	KAF GRUP SAG. HIZM. INS. SAN. VE TIC. LTD. STI.	SOFRAGRUP S.R.L.	Rg04-000198	24-08-2022
DM000368065	GEL LUBRIFIANT UREATRAL CU LIDOCAINĂ	ONEGEL	12.5 ML	KAF G27-12.5	Turcia	KAF GRUP SAG. HIZM. INS. SAN. VE TIC. LTD. STI.	SOFRAGRUP S.R.L.	Rg04-000198	24-08-2022
DM000368064	GEL LUBRIFIANT UREATRAL CU LIDOCAINĂ	ONEGEL	6 ML	KAF G27-6	Turcia	KAF GRUP SAG. HIZM. INS. SAN. VE TIC. LTD. STI.	SOFRAGRUP S.R.L.	Rg04-000198	24-08-2022

☒



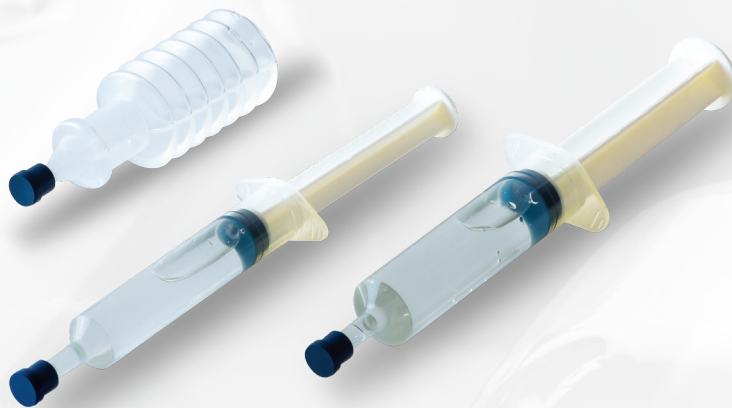
LUBRICANT GEL
WITH LIDOCAINE

OneGel

LUBRICANT GEL WITH LIDOCAINE (STERILE)

USAGE AREAS

- ONEGEL is a sterile, lubricating gel used to lubricate catheters and other medical devices during urethral, colon and rectal applications such as urethral catheterization, endoscopy and cystoscopy.
- It can be also used for rectal and colonic applications as a lubricant gel.
- The slider effect of the gel; Helps prevent trauma between urethral, colon and rectal mucosa and catheter/other medical devices. In this way, the patient is relieved and minimizes spasticity or discomfort caused by iatrogenic injury.



PRODUCT PROPERTIES

- Disposable.
- Soluable in water.
- Easy to use thanks to the syringe and accordion tube.
- Eliminates the risk of damage to tissue.
- Contains antiseptic Chlorhexidine Gluconate to eliminate the risk of infection.
- Lidocaine Hydrochloride is a local anesthetic agent used to prevent pain.
- It provides a painless catheterization with its anesthetic effect.
- Thanks to the lubricating feature provided by hydroxyethylcellulose, the patient relaxes and minimizes the spasticity and discomfort caused by iatrogenic injury.



Contains 2% Lidocaine



Anesthetic



Antiseptic

	ONEGEL 6ML	ONEGEL 11ML	ONEGEL 12,5GR
Product Reference Code	KAF G27-6	KAF G27-11	KAF G27-12,5
Packaging Type	Syringe	Syringe	Accordion Tube
GMDN	37717	37717	37717
Packaging	25 x 6ml / Box	25 x 11ml / Box	25 x 12,5gr / Box





USAGE

- Remove the syringe/accordion tube (6ml/11ml/12.5g) by tearing off the sterile packaging.
- Remove the stopper at the end of the syringe/accordion tube.
- Pour a drop of gel to facilitate application.
- After placing the syringe tip on the area to be lubricated, gently squeeze some ONEGEL Lidocaine Lubricating Gel by pressing the plunger of the syringe/accordion tube.



COMPOSITION

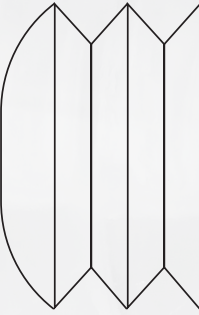
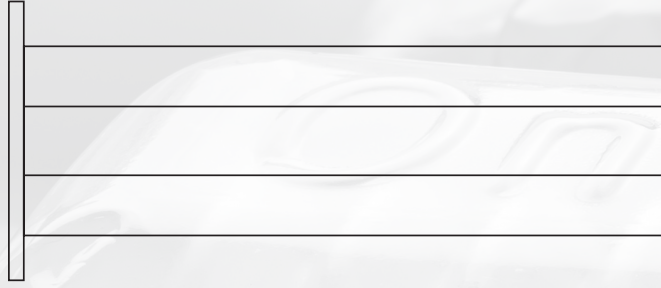
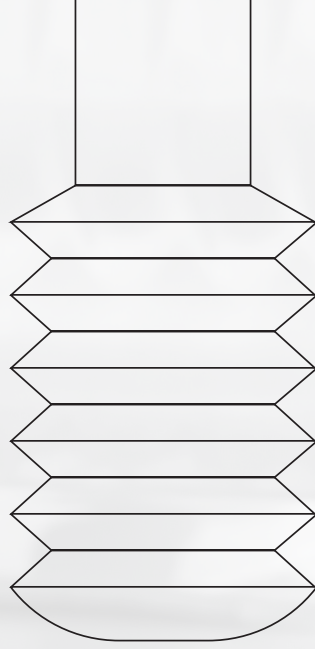
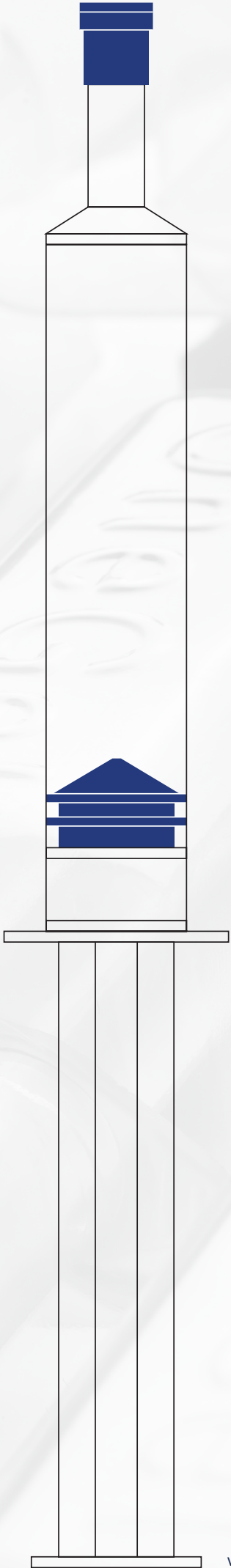
- Pure Water
- Propylene Glycol, Hydroxyethylcellulose (Lubricant)
- Lidocaine Hydrochloride (Local Anesthetic)
- Chlorhexidine Gluconate - 20% Concentration (Antiseptic)
- Methyl Hydroxybenzoate (Preservative)
- Propyl Hydroxybenzoate (Preservative)

It is a Class III Medical Device within
the scope of 93 / 42 / EEC Medical
Device Regulation



STERILE





KAFGRUP
SAĞLIK HİZMETLERİ

KAF GRUP SAĞLIK HİZMETLERİ İNŞ. SAN. VE TİC. LTD. ŞTİ.
www.kafgrup.com | www.wancare.com.tr | info@kafgrup.com | wan.care & kafgrup



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>"



TÜRK STANDARDLARI ENSTİTÜSÜ
TURKISH STANDARDS INSTITUTION

Full Quality Assurance Certificate

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

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>"

www.tse.org.tr / Necatibey Cad. No: 112 Bakanlıklar - ANKARA / +90 312 416 62 00

Bu belge hiçbir suretle tahrif edilemez, kısmen veya okunmasını zorlaştıracak şekilde çoğaltılamaz, kazıntı ve silinti yapılamaz.
This certificate cannot be altered, partially duplicated or creased for misunderstanding.



TÜRK STANDARTLARI ENSTİTÜSÜ

TURKISH STANDARDS INSTITUTION

Full Quality Assurance Certificate Certification History

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

Certificate No: 1783-MDD-238, Rev 00

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





TÜRK STANDARDLARI ENSTİTÜSÜ
TURKISH STANDARDS INSTITUTION

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



KAFGRUP SAĞLIK HİZMETLERİ	EC DECLARATION			
	Document No	Issue Date	Revision No	Revision Date
	TD. 03.51	10.06.2019	03	26.05.2021



EC DECLARATION OF CONFORMITY

Medical Devices Directive 93/42/EEC

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
Phone Number	:	Bardakçı Mah. Teknokent Sk. No:3 Tuşba/VAN
Web	:	+90 212 471 42 00
Mail	:	www.kafgrup.com
Production Address	:	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**

TD. 03.51

Issue Date

10.06.2019

Revision No

03

Revision Date

26.05.2021

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

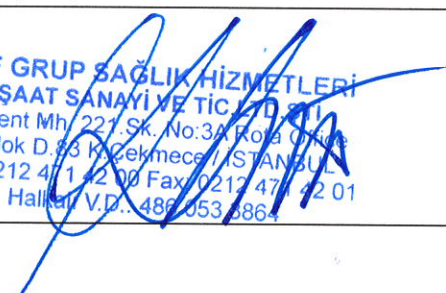
Manufactured to harmonized standards, and we declare that it complies with the provisions of the

KAFGRUP SAĞLIK HİZMETLERİ	EC DECLARATION			
	Document No	Issue Date	Revision No	Revision Date
	TD. 03.51	10.06.2019	03	26.05.2021

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	:	26.05.2021
Place of Declaration	:	İSTANBUL-TURKEY
Declarant	:	Gökmen Aydin / GENERAL MANAGER
Approval	:	 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