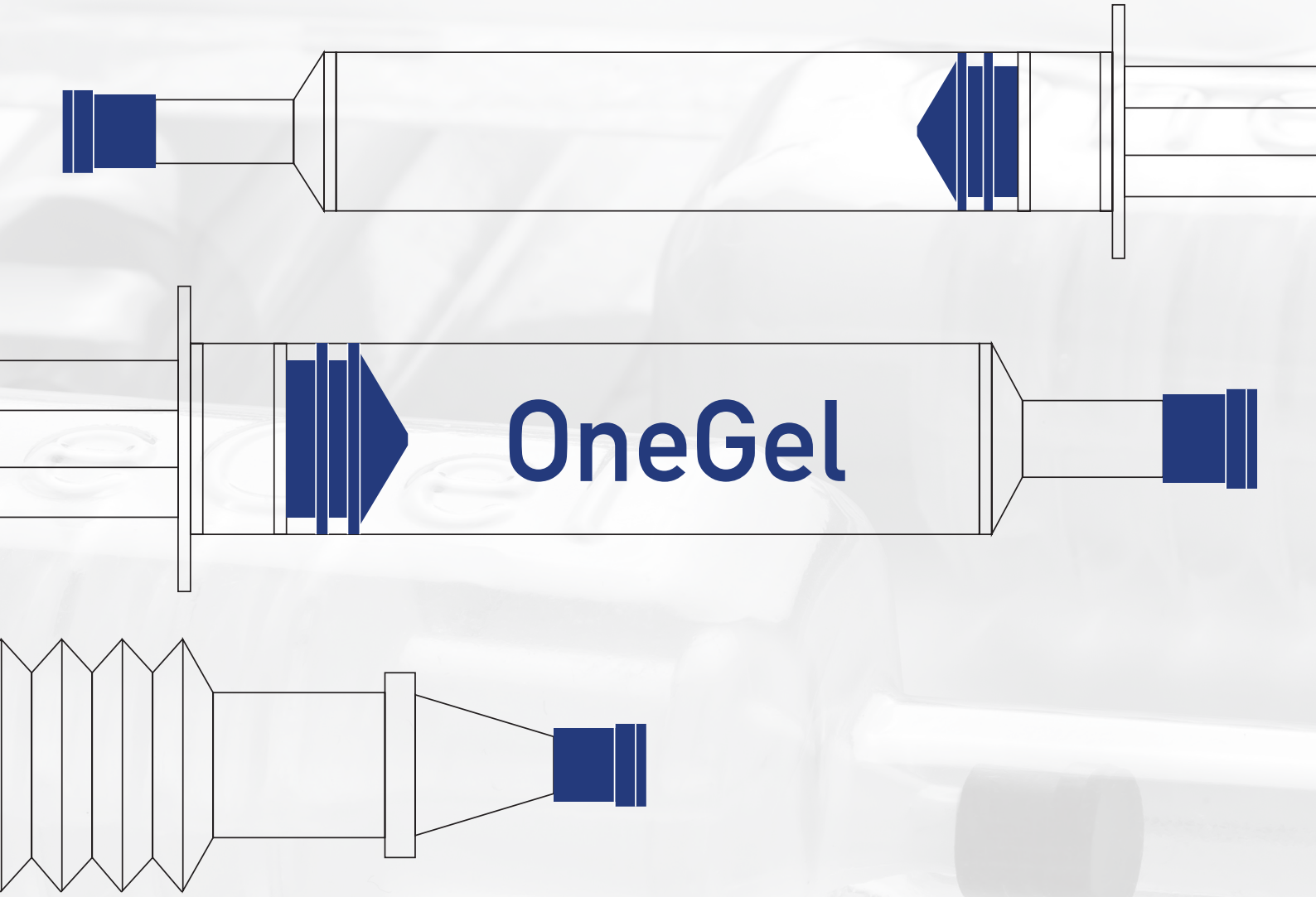


Digitally signed by Bunic Gheorghe
Date: 2024.06.02 15:17:41 EEST
Reason: MoldSign Signature
Location: Moldova

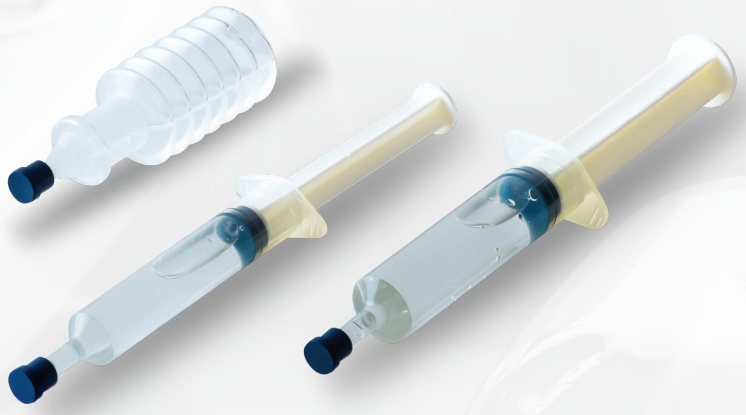
LUBRICANT GEL WITH LIDOCAINE

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.

%2 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

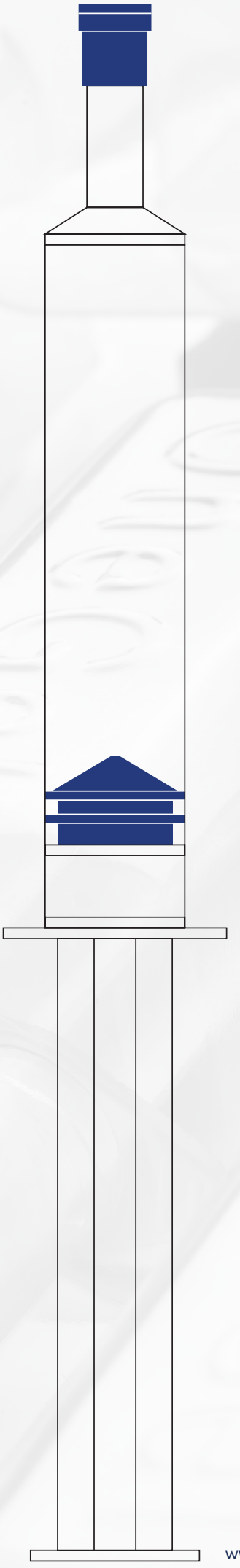
·Remove the syringe/accordion tube (6ml/11ml/12.5g) by tearing off the sterile packaging.
·Remove the stopper at the end of the syringe/accordion tube.
·Pour a drop of gel to facilitate application.
·After placing the syringe tip on the area to be lubricated, gently squeeze some ONEGEL Lidocaine Lubricating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

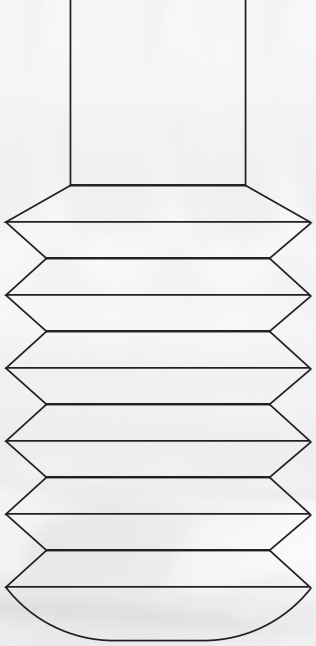
COMPOSITION

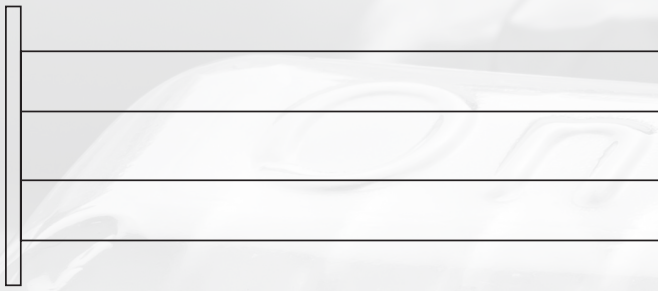
- Pure Water
- Propylene Glycol, Hydroxyethylcellulose (Lubricant)
- Lidocaine Hydrochloride (Local Anesthetic)
- Chlorhexidine Gluconate - 20% Concentration (Antiseptic)
- Methyl Hydroxybenzoate (Preservative)
- Propyl Hydroxybenzoate (Preservative

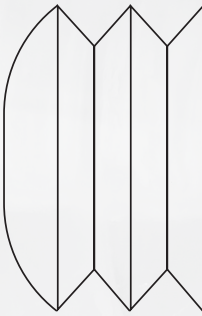
It is a Class III Medical Device within the scope of 93 / 42 / EEC Medical Device Regulation CE 1783

STERILE









KAF GRUP
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

KAF GRUP SAĞLIK HİZMETLERİ	EC DECLARATION			
	Document No	**Issue Date**	**Revision No**	**Revision Date**
	TD. 03.51	10.06.2019	03	26.05.2021

CE

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

KAF GRUP
SAĞLIK HİZMETLERİ

EC DECLARATION

Document No	Issue Date	Revision No	Revision Date
TD. 03.51	10.06.2019	03	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

KAF GRUP 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 Aytin / GENERAL MANAGER
Approval	:	KAF GRUP SAĞLIK HİZMETLERİ İNŞAAT SANAYİ VE TİC. LTD. ŞTİ. Atakent Mh. 221. Sk. No:3A Rota Ofis A Blok D.83 Küçükçekmece/İSTANBUL Tel: 0212 471 42 00 Fax: 0212 471 42 01 Halkalı V.D.: 486 053 3864

Kiwa Belgelendirme Hizmetleri A.Ş.
İ.T.O.S.B 9. Cadde No: 15
Tepeören Mevkii PK 34959
Tuzla İstanbul
Türkiye

Tel. +90 216 593 25 75
Faks +90 216 593 25 74
TR.Posta@kiwa.com
www.kiwa.com
www.1kiwa.com

Application Acceptance Letter

Subject/*Konu*: CE Certificate Application Acceptance Letter according to MDR 2017/745 Regulation
MDR 2017/745 Regülasyonuna göre CE Sertifikası Başvuru Kabul Yazısı

Date/Tarih: 14.05.2024

Reference Number/Referans Numarası: MY-24-002885
Application Number/Başvuru Numarası: : 00021207

To whom it may concern,
Sayın Yetkili,

This letter confirms that, **Kiwa Belgelendirme Hizmetleri A.Ş.** a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number **1984** on NANDO, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and accepted the application of manufacturer which is stated below.
Bu mektup, 2017/745 (AB) Yönetmeliğine (MDR) göre belirlenmiş ve NANDO'da 1984 numarasıyla tanımlanan bir Onaylanmış Kuruluş (NB) olan Kiwa Belgelendirme Hizmetleri A.Ş'nin, MDR Ek VII Bölüm 4.3, ilk alt paragrafına uygun olarak resmi bir başvuru aldığını ve aşağıda belirtilen üreticinin başvurusunu kabul ettiğini teyit eder.

Company Name/Şirket adı: KAF GRUP SAĞLIK HİZMETLERİ İNŞAAT SANAYİ VE TİC. LTD. ŞTİ.
Adress/Adres: Firma Adresi: Atakent Mah. 221. Sk. No:3A Rota Office a Blok D:83 Küçükçekmece/İstanbul
Adress/Adres:Üretim Yeri: Bardakçı Mah. Teknokent Sk. NO:3 Tuşba/VAN

On 11.05.2024, an application was made to our organization for the MDR of the products specified in Annex I and the necessary application documents were submitted to us. The application was accepted on 14.05.2024.

11.05.2024 tarihinde, **Ek-I'de** belirtilen ürünlerin MDR için kuruluşumuza başvuruda bulunulmuş ve gerekli başvuru dokümanları tarafımıza iletilmiştir. 14.05.2024 tarihinde başvurusu kabul edilmiştir.

Annex-I: Certificate Information

Ek-I: Sertifika bilgileri

Device name OR Basic UDI-DI (under MDR application) / *Cihaz adı veya Temel UDI-DI (MDR uygulaması altında)*	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage) / *MDR Cihaz sınıflandırması (üretici tarafından önerildiği ve ön başvuru aşamasında doğrulandığı şekilde)*	If the MDR device is a substitute device, identification of the corresponding MDD / *MDR cihazı ikame bir cihaz ise, ilgili MDD'nin tanımlanması*	MDD Certificate Reference(s) of the devices under MDR application, and the NB Identification / *MDR başvurusu kapsamındaki cihazların MDD Sertifika Referans(ları) ve NB Tanımlaması*
ONEGEL LUBRICANT GEL WIH LIDOCAINE(STERİL) / ONEGEL LİDOKAİN İÇERİKLİ KAYDIRICI JEL(STERİL) .	Class III / Sınıf III	The MDR device is not a substitute device. / MDR cihazı ikame bir cihaz değildir	TSE-Türk Standartları Enstitüsü Notified Body Number/Onaylanmış Kuruluş Numarası: 1783 Certificate Number/ Sertifika Numarası: 1783-MDD-238 / 1783-MDD-239
WANCARE MEDICAL DEVICE SURFACE DISINFECTANTS/WANCARE TIBBİ CİHAZ YÜZEY DEZENFEKTANLARI	Class IIa/ Sınıf IIa	The MDR device is not a substitute device. / MDR cihazı ikame bir cihaz değildir	TSE-Türk Standartları Enstitüsü Notified Body Number/Onaylanmış Kuruluş Numarası: 1783 Certificate Number/ Sertifika Numarası: 1783-MDD-211
WANCARE HIGH LEVEL MEDICAL DEVICE DISINFECTANTS (FOR INVASIVE DEVICES)/ WANCARE YÜKSEK DÜZEY TIBBİ CİHAZ DEZENFEKTANLARI(İNVAZİV CİHAZLAR İÇİN)	Class IIb/ Sınıf IIb	The MDR device is not a substitute device. / MDR cihazı ikame bir cihaz değildir	TSE-Türk Standartları Enstitüsü Notified Body Number/Onaylanmış Kuruluş Numarası: 1783 Certificate Number/ Sertifika Numarası: 1783-MDD-212

BARRIER CREAM INCONTITENCE WIPES / BARİYER KREMLİ İNKONTİNANS PED MENDİL	Class IIa/ Sınıf IIa	N/A	Self Decleration/ Self deklerasyon
BARRIER CREAM INCONTITENCE PERINEAL CLOTHS / BARİYER KREMLİ İNKONTİNANS PERİNE PEDİ	Class IIa/ Sınıf IIa	N/A	Self Decleration/ Self deklerasyon
WASH GLOVES WITH BARRIER CREAM / BARİYER KREMLİ KESE	Class IIa/ Sınıf IIa	N/A	Self Decleration/ Self deklerasyon
ONECARE INCONTINENCE BODY CARE SETS/ ONECARE İNKONTİNANS VÜCUT BAKIM SETLERİ	Class IIa/ Sınıf IIa	N/A	N/A

Kind Regards,
Saygılarımla,

Medical Devices Division Manager
Tıbbi Cihazlar Bölüm Yöneticisi
Mustafa Serkan Sevimli

KİWA
BELGELENDİRME HİZMETLERİ A.Ş.
Eski Ankara Asfaltı İstanbul Tuzla Org. San. Bölg.
9. Cad. No: 15 Tepeören/ Tuzla/ İSTANBUL/ TÜRKİYE
Tuzla V.D. 620 053 0464 Tic. Sic. No:3[illegible]
Mersis No: 0620007475700019

BELGELENDİRME MERKEZİ BAŞKANLIĞI

Continuation of Surveillance Activities Declaration Form for Certificates Under the scope of MDD

Company Name: KAF GRUP SAĞLIK HİZMETLERİ İNŞ. SAN. VE TİC. LTD. ŞTİ.

Certificate No: 1783-MDD-238

Certificate Scope: ONEGEL LUBRICANT GEL WITH LIDOCAINE (STERILE)

Declaration Form Date: 21.05.2024

Declaration Form Number: 01/1783-MDD-238

Dear Sir/Madam,

The European Commission (EU) No 2023/607 amending the transitional provisions of the "Regulations (EU) 2017/745 and (EU) 2017/746 of certain medical devices and in vitro diagnostic medical devices, in order to reduce the risk of non-supply of medical devices; and The Council Regulation was published in the EU Official Journal on 20 March 2023, to enter into force as of 20 March 2023.

In this context, devices covered by Directive 93/42/EEC, provided that they fulfill the conditions specified in this Regulation:

(A) Class III devices and class IIb implantable devices, excluding sutures, staples, dental fillings, dental brackets, dental crowns, screws, wedges, plates, wires, pins, clips and connectors, until 31 December 2027.

(B) Class IIb devices, class IIa devices other than those covered above, and class I devices placed on the market in sterile condition or with measuring function, until 31 December 2028,

may be placed on the market or put into service.

A request has been made by the company to continue surveillance activities according to the provisions of "Regulation (EU) No 2023/607 of the European Parliament and of the Council amending the transitional provisions of Regulation (EU) No 2017/745 and (EU) No 2017/746 for certain medical devices and in vitro diagnostic medical devices" for the devices within the scope of the certificate numbered 1783-MDD-238, and, if any, related Amendment Confirmation Forms issued by our notified body under the scope of the 93/42/EC Medical Device Directive, given in Annex-1.

The declaration prepared by the manufacturer stating that the extension conditions specified in the Regulation (EU) No 2023/607 of the European Parliament and of the Council are met, and in case the company makes an application to a notified body designated within the scope of the 2017/745 EU Medical Device Regulation (MDR), the confirmation form stating that the conformity assessment application has been made to the notified body designated under the MDR is given in Annex-2.

The evaluation of the documents submitted by the manufacturer within the scope of the request regarding the continuation of surveillance activities is given in Annex-2. It is hereby declared that the surveillance activities of the company in question will be continued until the date of 26.09.2024 within

the scope of the 93/42/EC Medical Device Directive by our notified body for the devices given in Annex-3.

21 / 05 / 2024

Deputy Director of Directives

Ali Fuat ÇOLAK
Direktifler Müdürü V.

Annexes:

1- Copy(s) of Document and Amendment Confirmation Form, if any
2- Documents submitted by the manufacturer regarding the extension request and its evaluation
3- Devices for which surveillance activities will continue

In order to confirm the validity of this statement prepared regarding the validity of surveillance activities, the contact information is given below.

Tel: +90312 416 6461

e-mail: mdd@tse.org.tr

Annex-3 Devices for which surveillance activities will continue

Device Name	Device Class
ONEGEL LUBRICANT GEL WITH LIDOCAINE (STERILE)	Class III

BELGELENDİRME MERKEZİ BAŞKANLIĞI

Continuation of Surveillance Activities Declaration Form for Certificates Under the scope of MDD

Company Name: KAF GRUP SAĞLIK HİZMETLERİ İNŞ. SAN. VE TİC. LTD. ŞTİ.

Certificate No: 1783-MDD-239

Certificate Scope: ONEGEL LUBRICANT GEL WITH LIDOCAINE (STERILE)

Declaration Form Date: 23.05.2024

Declaration Form Number: 01/1783-MDD-239

Dear Sir/Madam,

The European Commission (EU) No 2023/607 amending the transitional provisions of the "Regulations (EU) 2017/745 and (EU) 2017/746 of certain medical devices and in vitro diagnostic medical devices, in order to reduce the risk of non-supply of medical devices; and The Council Regulation was published in the EU Official Journal on 20 March 2023, to enter into force as of 20 March 2023.

In this context, devices covered by Directive 93/42/EEC, provided that they fulfill the conditions specified in this Regulation:

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may be placed on the market or put into service.

A request has been made by the company to continue surveillance activities according to the provisions of "Regulation (EU) No 2023/607 of the European Parliament and of the Council amending the transitional provisions of Regulation (EU) No 2017/745 and (EU) No 2017/746 for certain medical devices and in vitro diagnostic medical devices" for the devices within the scope of the certificate numbered 1783-MDD-239, and, if any, related Amendment Confirmation Forms issued by our notified body under the scope of the 93/42/EC Medical Device Directive, given in Annex-1.

The declaration prepared by the manufacturer stating that the extension conditions specified in the Regulation (EU) No 2023/607 of the European Parliament and of the Council are met, and in case the company makes an application to a notified body designated within the scope of the 2017/745 EU Medical Device Regulation (MDR), the confirmation form stating that the conformity assessment application has been made to the notified body designated under the MDR is given in Annex-2.

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the scope of the 93/42/EC Medical Device Directive by our notified body for the devices given in Annex-3.

21 / 05 / 2024

Deputy Director of Directives

Ali Fuat ÇOLAK
Direktifler Müdürü V.

Annexes:

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2- Documents submitted by the manufacturer regarding the extension request and its evaluation
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Tel: +90312 416 6461

e-mail: mdd@tse.org.tr

Annex-3 Devices for which surveillance activities will continue

Device Name	Device Class
ONEGEL LUBRICANT GEL WITH LIDOCAINE (STERILE)	Class III

AGENȚIA MEDICAMENTULUI ȘI DISPOZITIVELOR MEDICALE

REGISTRUL DE STAT AL DISPOZITIVELOR MEDICALE

Tip	Denumire
I.2. Declarația de conformitate CE	Declaratia de conofmritatre CE
I.3. Certificatul CE	Certificat CE DE
I.3. Certificatul CE	Certificat CE FQA

Введите текст для поиска...

Nr	Denumire	Den.comerc.	Model	Nr. catalog	Tara	Producatorul	Reprezentant	Ordin	Data	Cod vamal
DM000368065										
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	

Содержит([Code], 'DM000368065') Очистить