LUBRIGIMA LUBRICANT GEL - bottle 250 ml

Product Code	29960
Unit of sale	1 pc
Minimum order	1
Type	Medical device
Class	II A

UK-REP	No
CH-REP	No

RDM (NSIS)	2611970
CND	V9099
EAN/UPC	8683229601597
PARAF	903143372
GMDN	33587

Description

LUBRIGIMA - 250 ml

Facilitates instruments insertion during gyn. examinations. Its special composition and high transparency do not alter the visual image when optical instruments are used.

It does not contain spermicides and does not grease or stain.
It has acid Ph and good electrical conductivity.
Water soluble.
Well absorbed by the skin, does not irritate the mucosa.
Latex free.

Digitally signed by Volcovschi Mihai
Date: 2026.07.30 17:26:42 EEST
Reason: MoldSign Signature
Location: Moldova
MOLDOVA EUROPEANĂ

AT UYGUNLUK BEYANI
EC DECLARATION OF CONFORMITY

ÜRETİCİ FİRMA ADI: *MANUFACTURER NAME:*	TURKUAZ SAĞLIK HİZMETLERİ MEDİKAL TEMİZLİK KİMYASAL ÜRÜNLER SANAYİ VE TİCARET ANONİM ŞİRKETİ
ADRES: *ADDRESS:*	Akçaburgaz Mah. Muhsin Yazıcıoğlu Cad. No:45/5 Esenyurt / İstanbul / Türkiye
TELEFON: *PHONE:*	+902124286848
E-MAIL:	info@turkuazsaglik.com.tr
WEB SITE:	www.turkuazsaglik.com.tr
The Information of SRN Number:	TR-MF-000015402
MARKA: *TRADE MARK:*	Lubrigima
ÜRÜN ADI: *PRODUCTS:*	Steril Olmayan Kayganlaştırıcı Jel Non-Sterile Lubricating Gel
ÜRÜNLER: *PRODUCTS:*	

Brand	Ref No	Version No	Model	Packaging	UDI-DI
Lubrigima	29960	Y1015.105.0001	5 g	Plastic Bottle	8683229601597

GMDN KODU: *GMDN CODE:*	33587
SINIFLANDIRMA: *CLASSIFICATION:*	Annex IX of The MDD 93/42 EEC Class IIa, Rule 5
UYGUNLUK DEĞERLENDİRME YOLU: *CONFORMITY ASSESSMENT ROUTE:*	MDD 93/42/EEC ANNEX V
UYGULANABİLİR STANDARTLAR: *APPLICABLES STANDARDS:*	EN ISO 9001:2015, EN ISO 13485:2016+A11:2021, EN ISO 14971:2019+A11:2021,ISO/TR 24971:2020, TS EN ISO 14644-1:2015, TS EN ISO 14644-2:2015, TS EN ISO 14644-3:2019,EN ISO 10993-1:2020, EN ISO 10993-5:2009, EN ISO 10993-10:2023, EN ISO 10993-11:2018, EN ISO 10993-18:2020+A1:2023, EN ISO 10993-17:2023, EN 62366-1:2015/A1:2020,TS ISO 2859-1:1999/ AMD 1:2011, EN ISO 15223-1:2021, ISO 20417:2021, EN 17141:2020
TEKNİK DOSYA/*TECHNICAL FILE:* **SAKLAMA ADRESİ/***RETAIN ADDRESS:* **SORUMLU KİŞİ/***RESPONSIBLE PERSON:*	TD No/TF No: TD-17 Yukarıdaki adreste tutulmaktadır. / Retained at the above address. Resp. Person: Hanifi Karahan Bozkurt

ONAYLANMIŞ KURULUŞ ADI VE NUMARASI/NOTIFIED BODY NAME &ID:	UDEM - 2292
CE BELGESİ SERTİFİKA NUMARASI/CE CERTIFICATE NUMBER:	M.2018.106.9536
CE BELGESİ BİTİŞ TARİHİ/CE CERTIFICATE EXPIRATION DATE:	27/05/2024

The Devices listed in this declaration of conformity are fulfilling the requirement of MDD 93/42/EC amended by 07/47/EC and are under the sole responsibility of Turkuaz Sağlık Hizmetleri Medikal Temizlik Kimyasal Ürünler Sanayi ve Ticaret A.Ş.

Bu deklarasyonda listelenen tüm cihazlar MDD 93/42/EC değiştirilen 07/47/EC nin gerekliliklerini karşılamaktadır ve tamamen Turkuaz Sağlık Hizmetleri Medikal Temizlik Kimyasal Ürünler Sanayi ve Ticaret AiŞ.' nin sorumluluğu altındadır.

Yer, Place: *Istanbul* ***Tarih, Date:*** *14.07.2025*	Seçil PALA Kalite Direktörü Quality Director TURKUAZ SAĞLIK HİZMETLERİ MEDİKAL TEMİZLİK KİMYASAL ÜRÜNLER SAN ve TİC.A.Ş. Akçaburgaz Mah. Muhsin Yazıcıoğlu Cad. No:45/5 Postakodu :34522 Esenyurt / İSTANBUL Tel:+90 212 428 68 48 Fax:+90 212 428 68 53 Yenikapı No:871 055 40 10 Tic.Sic.No:450836

Turkuaz Sağlık Hizmetleri Medikal Temizlik Kimyasal Ürünler San. ve Tic. A.Ş.
Akçaburgaz Mahallesi Muhsin Yazıcıoğlu Caddesi No:45/5 34522 Esenyurt, İstanbul - TÜRKİYE
T +90 212 428 68 48 Pbx www.turkuazsaglik.com.tr | info@turkuazsaglik.com.tr

KLY® GLEITGEL

DE

PRODUKTNAME: KLY® GLEITGEL
INHALT: Deionisiertes Wasser, natürliches Glycerin, MonopropylenGlykol, Hydroxyethyl Cellulose, Methylhydroxybenzoat, Zitronensäure
VERWENDUNGSZWECK: Endoskopie, Koloskopie, gynäkologische Untersuchungen, rektoskopische Anwendungen, bei Katheter-Anwendungen wird es auch als vaginales Gleitmittel verwendet.
VERWENDUNG: Das Öffnen der Tube: Schrauben Sie die Kappe der Tube. Dann drehen Sie die Kappe um und drücken gegen die Oberseite der Tube, um ein Loch zu machen. Bitte verwenden Sie Handschuhe bei der Verwendung von KLY Gleitgel bei Patienten und schmieren Sie eine ausreichende Menge, um eine Schicht zu bilden. Waschen Sie sich nach dem Gebrauch.
Öffnen der Verpackung: Zur Nutzung vorsichtig an den markierten Stellen öffnen.
SICHERHEITSMASSNAHMEN: Sicherheitshinweise: Wenn die Abdeckung geöffnet oder die Verpackung beschädigt ist, kann keine Garantie gewährt werden.
KONTRAINDIKATIONEN: Es sind keine bekannten Gegenwirkungen für KLY Gleitgel bekannt.
ÜBERDOSIS UND NEBENWIRKUNGEN: Bis jetzt wurden bei einer Überdosierung keine Symptome beobachtet.
SENSIBILITÄT GEGEN GLYCERIN: Glycerin hilft bei der Befeuchtung der Haut. Manche Hauttypen haben zeigen eine sensible Wirkung gegen Glycerin, dies sollte bei der Anwendung berücksichtigt werden.
PRODUKTBESCHREIBUNG: Transparent, klares, wasserlösliches Gleitgel
UNTERSCHIEDLICHE VERPACKUNGEN: Tube: 42 g, 50 g, 82 g, 113,4 g, 100 g, 250 g, 1000 g
EINWEG-BEUTEL: 2,5 g, 3 g, 3,5 g, 4 g, 4,5 g, 5 g, 10 g
LAGERBEDINGUNGEN:
Aufbewahren bei 5-30°C in einer verschlossenen Tube oder Kiste.
AUßERHALB DER REICHWEITE VON KINDERN AUFBEWAHREN.

BRAND / KLY

KLY® GEL LUBRICANTE

ES

NOMBRE DEL PRODUCTO: KLY® GEL LUBRICANTE
INFORMACIÓN SOBRE LOS COMPONENTES: Agua Desionizada, Glicerina Natural, Monopropileno Glicol, Hidroxietilo Celulosa, Metilhidroxibenzoato, Ácido Cítrico
LOS ÁMBITOS DE UTILIZACIÓN: La endoscopia, colonoscopia, exámenes ginecológicos, aplicaciones rectoscopios, también se utiliza como lubricante vaginal para las aplicaciones de catéter.
USO: Abrir el tubo: Desenrosque la tapa del tubo. A continuación, gire alrededor de la tapa y presione contra la parte superior del tubo con el fin de hacer un agujero. Por favor, aplicar el gel lubricante KLY en pacientes utilizando guantes y aplicar una cantidad suficiente para formar una capa.
Lávese después de su uso.
Abrir ambalaje: Para usar abrir cuidosamente en los lugares marcados.
PRECAUCIONES DE SEGURIDAD: Medidas de seguridad: Si la cubierta está abierta o embalaje está dañado, no hay garantía de producto.
EFECTOS REVERSOS: No hay contraindicaciones conocidas.
SOBRE DOSIS Y EFECTOS SECUNDARIOS: No se observaron síntomas cuando se utiliza en sobredosis
SENSIBILIDAD GLICERINA: Algunos tipos de piel pueden tener una sensibilidad hacia la glicerina, por lo que esto debe ser considerado durante su uso. Glicerina permite la hidratación de la piel.
DESCRIPCIÓN DEL PRODUCTO: Transparente, de color claro, soluble en agua, lubricante gel
Tipos de envases diferentes: Tubo: 42 g, 50 g, 82 g, 113,4 g , 100 g, 250 g, 1000 g
BOLSITA DESECHABLE DE: 2,5 g, 3 g, 3,5 g, 4 g, 4,5 g, 5 g, 10 g
CONDICIONES DE ALMACENAJE: Almacenar a 5-30°C en un tubo sellado o caja.
MANTENER FUERA DEL ALCANCE DE LOS NIÑOS

TURQUIA MARCA / KLY

جل مزحلق KLY®

AR

اسم المنتج :
جل مزحلق KLY®
معلومات عن المكونات:
ماء منزوع الأيونات ، جليسرين طبيعي ، جلايكول مونوبروبيلين ، هيدروكسي إيثيل السليلوز ، ميثيل هيدروكسي بنزو ، حمض الستريك.
الغرض من الاستخدام :
يتم استخدام التنظير ، تنظير القولون ، الفحوصات النسائية ، تطبيقات التنظير أيضا للتزحلق المهبلي في تطبيقات القسطرة.
طريقة الاستعمال:
فتح الأنبوب: افتح الغطاء عن طريق تدوير الغطاء التي تقع على الجزء العلوي من الأنبوب. وبعد ذلك تقلب الأنبوب وبمساعدة طرف مدبب في الداخل تضغط على فم الأنبوب وتثقب الانبوب. استخدام كمية كافية من جل لوبريكنت لإنشاء طبقة على السطح بمساعدة قفاز أو أداة أخرى لاستخدامها في المرضى. ويغسل بعد الاستعمال.
طريقة فتح الكيس: تفتح الكيس بعناية من الأماكن المميز.
احتياطات السلامة:
احتياطات السلامة: لا يمكن إعطاء ضمانات المنتج إذا كانت العبوة مفتوحة أو تالفة.
موانع الاستعمال:
لا يوجد موانع معروفة لـ جل لوبريكنت KLY
الجرعة الزائدة والآثار الجانبية:
لم يتم العثور على أعراض إذا تم استخدام جرعة زائدة .
حساسية للغليسيرين: يوفر الغليسيرين بترطيب البشرة. بما أن بعض أنواع البشرة حساسة للغليسيرين ، يجب أخذ هذا التأثير بعين الاعتبار أثناء الاستخدام.
تعريف المنتج:
شفاف اللون ، قابلة للذوبان في الماء ، جل مزحلق
أنواع مختلفة من التعبئة:
أنبوب: 42 غرام ،50غرام ، 82 غرام ، 113.4 غرام ، 100 غرام 1000 غرام ، 250 غرام
كيس للاستخدام لمرة واحدة: 2.5 غرام ، 3 غرام ، 3.5 غرام ، 4 غرام ، 4.5 غرام ، 5 غرام ، 10 غرام
شروط التخزين:
تخزن في أنبوب مغلق او في علبة ما بين درجات حرارية 5-30 درجة مئوية.
يبقيه بعيدا عن متناول الأطفال.
معلومات حول المصنع والعلامة التجارية:

العلامة التجارية KLY :

ГЕЛЬ ЛУБРИКАНТ KLY®

RU

НАИМЕНОВАНИЕ ПРЕПАРАТА: ГЕЛЬ ЛУБРИКАНТ KLY®
СВЕДЕНИЯ О СОСТАВЕ: В каждых 100 г. геля KLY 16 г. глицерина, консерванты
ОБЛАСТИ ПРИМЕНЕНИЯ: Эндоскопия, колоноскопия, при применении гинекологического ЗЕРКАЛА, ректоскопия, медицинское обследование при помощи зондирования, у женщин, испытывающих трудности во время секса в связи с недостатком естественной смазки, в качестве лубриканта во время полового акта.
ПРОТИВОПОКАЗАНИЯ: Индивидуальная непереносимость глицерина. Необходимо учитывать, что некоторые типы кожи обладают чувствительностью к глицерину. Глицерин обладает увлажняющими кожу качествами.
СПОСОБ ПРИМЕНЕНИЯ: Открутите крышку на тюбике. После чего при помощи острого наконечника, имеющегося на наружной стороне крышки, проколите защитную пленку на горлышке тюбика. Для применения при помощи рук или какого-либо прибора нанесите необходимое количество геля-лубриканта KLY до образования тонкого слоя на коже пациента. После применения смойте остатки геля.
Вскрытие упаковки: Для использования аккуратно откройте упаковку в отмеченном месте.
МЕРЫ ПРЕДОСТОРОЖНОСТИ: Меры **ПРЕДОСТОРОЖНОСТИ:** Не используйте препарат, крышка которого открыта или нарушена упаковка.
ПЕРЕДОЗИРОВКА И ПОБОЧНЫЕ ЭФФЕКТЫ: В случаях передозировки препарата никаких отрицательных симптомов не наблюдалось. Однако при индивидуальной непереносимости препаратра может наблюдаться тошнота или рвота. В случае усиления подобных симптомов немедленно обратитесь к врачу.
ОПИСАНИЕ ПРЕПАРАТА: Прозрачный, светло-желтого цвета, растворимый в воде гель-смазка
ФОРМЫ УПАКОВКИ: Тюбики по: 42 г. 50 г. 82 г. 113,4 г. или 100 мл. 1000 мл.
Одноразовые пакетики по 5 г. или 10 г.
УСЛОВИЯ ХРАНЕНИЯ: 2,5 г. 3 г. 3,5 г. 4 г. 4,5 г. 5 г. 10 г. бутылка: 250мл.
Хранить в плотно закрытом тюбике или коробке при температуре 5-30 °C.
ХРАНИТЕ В МЕСТАХ, НЕДОСТУПНЫХ ДЕТЯМ.

KLY® ΓΚΕΛ ΛΥΠΑΝΣΗΣ

EL

ΟΝΟΜΑΣΙΑ ΠΡΟΪΟΝΤΟΣ: KLY® ΓΚΕΛ ΛΥΠΑΝΣΗΣ
ΣΥΝΘΕΣΗ: Απιονισμένο Νερό, Φυσική Γλυκερίνη, Μονοπροπυλενογλυκόλη, Υδροξυαιθυλοκυτταρίνη, Υδροξυβενζοϊκό Μεθύλιο, Κιτρικό Οξύ
ΠΡΟΒΛΕΠΟΜΕΝΗ ΧΡΗΣΗ: Αυτό το γκέλ χρησιμοποιείται για εφαρμογές ενδοσκόπησης, κολονοσκόπησης, γυναικολογικών εξετάσεων, πρωκτοσκόπησης, εφαρμογών καθετήρα, καθώς και την λίπανση του κόλπου.
ΟΔΗΓΙΕΣ ΧΡΗΣΗΣ: Για να ανοίξετε το σωλήνα: Αφαιρέστε και γυρίστε το καπάκι και μετά τρυπήστε το σωλήνα με αυτό. Εφαρμόστε το Γκέλ Λίπανσης στα γάντια ή το όργανο σε επαρκή ποσότητα ώστε να σχηματίσει ένα φιλμ πάνω από το μέρος που θα είναι σε επαφή με τον ασθενή. Ξεπλύνετε μετά τη χρήση.
Για να ανοίξετε το φακελάκι: Ανοίξτε προσεκτικά από το επισημασμένο μέρος.
ΙΔΙΑΙΤΕΡΕΣ ΠΡΟΦΥΛΑΞΕΙΣ: Προφυλάξεις: Εάν το δοχείο είναι κατεστραμμένο ή ανοιχτό, το προϊόν δεν είναι εγγυημένο.
ΑΝΤΕΝΔΕΙΞΗ: Δεν υπάρχει καμία γνωστή αντένδειξη
ΥΠΕΡΔΟΣΟΛΟΓΙΑ ΚΑΙ ΠΑΡΕΝΕΡΓΕΙΕΣ
Δεν υπάρχουν γνωστά συμπτώματα για τη χρήση υπερδοσολογίας.
Ευαισθησία Στη Γλυκερίνη: Η γλυκερίνη έχει μαλακτικές ιδιότητες. Πρέπει να λαμβάνονται οι προφυλάξεις κατά τη χρήση του έρχονται σε άτομα που έχει ευαισθησία στη γλυκερίνη.
ΑΝΑΓΝΩΡΙΣΗ: Διαφανής, υδατοδιαλυτό, χωρίς λιπαρά και ζελέ.
ΜΟΡΦΗ ΠΑΡΟΥΣΙΑΣΗΣ: Σωλήνες Περιέχουν καθώς: 42 γρ, 50 γρ, 82 γρ, 113,4 γρ, 100 γρ ή 250 γρ, 1000 γρ
Φακελάκια Περιέχουν καθώς: 2,5 γρ 3 γρ, 3,5 γρ 4 γρ, 4,5 γρ 5 γρ 10 γρ
ΟΔΗΓΙΕΣ ΔΙΑΤΗΡΗΣΗΣ: Διατηρήστε σε θερμοκρασία μεταξύ 5-30° C
ΝΑ ΦΥΛΑΣΣΕΤΑΙ ΜΑΚΡΙΑ ΑΠΟ ΤΑ ΠΑΙΔΙΑ

ΕΜΠΟΡΙΚΟ ΣΗΜΑ / KLY

KLY® KAYGANLAŞTIRICI JEL

TR

ÜRÜN ADI: KLY® KAYGANLAŞTIRICI JEL
İÇERİK BİLGİSİ: Deionized water, Natural Glycerin, Monopropylen Glycol, Hydroxy Ethyl Cellulose, Methyl Hydroxybenzoate, Citric Acid
KULLANIM AMACI: Endoskopi, kolonoskopi, jinekolojik muayeneler, rektoskopi uygulamaları, sonda uygulamalarında ayrıca vajinal lubrikasyon için kullanılır.
KULLANIM ŞEKLİ: Tüp Açma: Tüpün başındaki kapağı çevirerek açınız. Ardından ters çevirerek iç kısımdaki sivri uç yardımı ile tüpün ağzına bastırmak koşulu ile tüpü deliniz. Lubrikant Jeli, hastalarda kullanmak için eldiven ya da bir başka gereç yardımı ile yüzeyde bir film tabakası oluşturacak şekilde yeterli miktarda kullanınız. Kullanımdan sonra yıkayınız.
Saşe açma: İşaretli yerden dikkatli bir şekilde açılarak kullanılır.
GÜVENLİK ÖNLEMLERİ: Güvenlik Önlemleri: Ambalajın kapağı açık veya hasarlı ise ürün garantisi verilemez.
KONTRAENDİKASYON: KLY Lubricant Jel'in bilinen bir kontraendikasyonu yoktur.
AŞIRI DOZ VE YAN ETKİLER: Aşırı dozda kullanılması halinde herhangi bir semptoma rastlanılmamıştır.
GLISERINE KARŞI DUYARLILIK: Gliserin cildin nemlenmesini sağlar. Bazı cilt tipleri gliserine karşı duyarlı olduğundan kullanımı esnasında bu etki göz önünde bulundurulmalıdır.
ÜRÜN TANIMI: Şeffaf renginde, suda çözünebilen, kayganlaştırıcı jel
FARKLI AMBALAJ ŞEKİLLERİ: Tüp: 42 g, 50g, 82 g, 113,4 g, 100 g, 250 g, 1000 g
Tek kullanımlık Saşe: 2,5 g, 3 g, 3,5 g, 4 g, 4,5 g, 5 g 10 g
DEPOLAMA ŞARTLARI: Kapalı bir tüp yada kutuda 5-30°C arasında saklayınız.
ÇOCUKLARIN ERİŞEMEYECEĞİ BİR YERDE SAKLAYINIZ.

MARKA/KLY

Paket hasarlı ise kullanmayınız / Do not use if package is damaged / يجب عدم استعمال المنتج اذا كانت العبوة متضررة	Güneş ışığından uzak tutunuz / Keep away from sunlight / يجب المحافظة على المنتج بعيدا عن أشعة الشمس	Kuru ortamda saklayınız / Keep Dry. / يجب المحافظة على المنتج في وسط جاف
Saklama Sıcaklığı / Storage Temperature / درجة حرارة التخزين	Dikkat / Caution / انتباه	Katalog Numarası / Catalogue Number / رقم الكتالوج
Kullanım kılavuzuna bakınız / Consult instructions for use / يجب مراعاة تعليمات الاستخدام	Üretici / Manufacturer / المصنع	"LOT" numarası / Batch Code / رقم الدفعة
Üretim Tarihi / Date of Manufacture / تاريخ الانتاج	Son kullanma tarihi (gg/ yil) / Expiration Date (Months/ Year) / تاريخ انتهاء الصلاحية (شهر/ السنة)	Tek kullanımlıktır. / Do not re-use. / وحد الاستعمال
Nonsteril / Non-sterile / غير معقم	Tıbbi cihaz / Medical Device / جهاز طبي	

Rev:10/23.02.2023

Turkuaz Sağlık Hizmetleri, Medikal, Temizlik Kimyasal Ürünler San. ve Tic. A.Ş.
Akçaburgaz Mah. Muhsin Yazıcıoğlu Cad. No:45/5 34522 Esenyurt / İstanbul / Türkiye
T +90 212 428 6848 Pbx **F** +90 212 428 6853
info@turkuazsaglik.com.tr / www.**turkuazsaglik**.com.tr

CE 2292

Made in Turkey Discover the potential

KLY® LUBRICATING JELLY

EN

PRODUCT NAME: KLY® LUBRICATING JELLY
COMPOSITION: Deionized water, Natural Glycerin, MonopropylenGlycol, Hydroxy Ethyl Cellulose, Methyl Hydroxybenzoate, Citric Acid
INTENDED USE: This gel is used in endoscopy, colonoscopy, gynecological examinations, rectal endoscopic, catheter operations, also used for vaginal lubrication.
INSTRUCTION FOR USE: To Open The Tube: Remove and reverse the cap then puncture the tube with it. Apply Lubricating Jelly to the gloves or the instrument in sufficient amount so that it forms a film over the area that comes in contact with patient. Wash off after use.
To Open The Sachet: Open carefully from marked area.
SPECIAL PRECAUTIONS: Precautions: If container is damaged or opened, the Product is not guaranteed.
CONTRAINDICATION: There is no known contraindication
OVERDOSAGE AND SIDE EFFECTS: There is no known symptoms for overdose usage.
SENSITIVITY TO GLYCERIN: Glycerin has emollient properties. Precautions Shall be taken when using the gel in people with sensitivity to glycerin.
IDENTIFICATION: Transparent, water-soluble, greaseless and jelly.
PRESENTATION: Tubes Containing either: 42 g, 50 g, 82 g, 113,4 g, 100 g, 250 g, 1000 g
SACHETS CONTAINING EITHER: 2,5 g, 3 g, 3,5 g, 4 g, 4,5 g, 5 g, 10 g
STORAGE INSTRUCTIONS: Store between 5-30°C
KEEP OUT OF REACH OF CHILDREN

TRADEMARK / KLY

KLY® GEL LUBRIFIANT

FR

NOM DU PRODUIT: KLY® GEL LUBRIFIANT
COMPOSITION: Eau Désionisée, Glycérine Naturelle, Glycol De Mono Propylène, Éthyle De Hydroxyle Cellulose, Méthyle Hydrox Benzoate, Acide Citrique
UTILISATION PREVUE: Ce gel est utilisé dans l'endoscopie, la colonoscopie, les examens gynécologiques, l'endoscopie rectal, les opérations de cathéter, utilisé aussi pour la lubrification vaginale.
INSTRUCTION POUR L'UTILISATION: Ouvrir le Tube: Enlevez et reverser le plafond alors le tube avec cela. Appliquez la gelée lubrifiante aux gants ou à l'instrument dans une quantité suffisante, pour qu'il forme un film sur la zone qui entre en contact avecle patient. Lavez-vous d'après l'utilisation.
Ouvrir Le Sachet: Ouvrez soigneusement de la zone marquée.
PRÉCAUTIONS SPÉCIALES: Précautions: Si le récipient est endommagé ou ouvert, le produit n'est pas garanti.
CONTRE-INDICATION: Il n'y a aucune contre-indication connue
SURDOSAGE ET EFFETS SECONDAIRES: Il n'y a aucun symptôme connu pour l'usage d'overdose.
SENSIBILITÉ À LA GLYCÉRINE: la Glycérine a des propriétés émollientes. Des précautions seront pris en utilisant le gel dans les gens avec la sensibilité à la glycérine.
IDENTIFICATION: Transparent, d'eau et soluble, sans graisse et sans gelée.
PRÉSENTATION: Tubes c contenant une quantité de: 42 g, 50 g, 82 g, 113,4 g, 100 g, 250 g, 1000 g
SACHETS CONTENANT UNE QUANTITÉ DE: 2,5 g, 3 g, 3,5 g, 4 g, 4,5 g, 5 g, 10 g
INSTRUCTIONS DE STOCKAGE: Emmagasinez sous une température de 5 à 30°C
GARDEZ HORS DE PORTÉE DES ENFANTS

TRADEMARK/KLY

KLY® GEL LUBRIFICANTE

IT

NOME DEL PRODOTTO: KLY® GEL LUBRIFICANTE
INFORMAZIONI SUGLI INGREDIENTI: Acqua Deionizzata, Glicerina Naturale, Monopropilenglicole, Idrossietilcellulosa, Metilidrossibenzoato, Acido Citrico
DESTINAZIONE D'USO: Questo gel è utilizzato in endoscopia, colonscopia, esami ginecologici, applicazioni di rettoscopia, applicazioni di catetere e anche per la lubrificazione vaginale.
ISTRUZIONI PER L'USO: Per aprire il tubo: Rimuovere il tappo nella parte superiore del tubo e perforare il tubo spingendo la bocca del tubo con la punta del tappo. Applicare il Gel Lubrificante KLY, con l'aiuto di guanti o di un altro strumento, in una quantità sufficiente a formare lo strato superficiale. Lavare dopo l'uso.
APERTURA DELLA BUSTINA: Usare il prodotto dopo aver aperto con cautela la bustina alle posizione contrassegnata.
PRECAUZIONI SPECIALI: Precauzioni: se il contenitore è danneggiato o aperto, il prodotto non si considera garantito.
CONTROINDICAZIONE: Non ci sono controindicazioni conosciute.
SOVRADOSAGGIO ED EFFETTI COLLATERALI: Non ci sono sintomi noti in caso di overdose.
SENSIBILITÀ ALLA GLICERINA: La glicerina ha proprietà emollienti. Perciò, tali caratteristiche devono essere prese in considerazione quando il gel si utilizza nelle persone con sensibilità alla glicerina.
DESCRIZIONE DEL PRODOTTO: Gel lubrificante, trasparente, di colore ambrato chiaro e solubile in acqua.
DIVERSE FORME DI IMBALLAGGIO: Tubo: 42 g, 50 g, 82 g, 113,4 g, 100 g, 250 g, 1000 g
BUSTINE MONOUSO: 2,5 g, 3 g, 3,5 g, 4 g, 4,5 g, 5 g, 10 g
CONDIZIONI DI CONSERVAZIONE: Conservare a 5-30°C in un tubo chiuso o sigillato.
CONSERVARE FUORI DALLA PORTATA DEI BAMBINI.

MARCHIO / KLY

KLY® GELÉIA LUBRIFICANTE

PT

NOME DO PRODUTO: Kly®Geléia lubrificante
COMPOSIÇÃO: Água deionizada, glicerina natural, monopropileno glicol, hidroxietilcelulose, hidroxibenzoato de metila, ácido cítrico
USO PRETENDIDO: Este gel é usado em endoscopia, colonoscopia, exames ginecológicos, endoscopia retal, operações de cateter, também usado para lubrificação vaginal.
INSTRUÇÕES: Para abrir o tubo: remova e vire a tampa e, em seguida, perfure o tubo com. Aplique gelatina lubrificante nas luvas ou no instrumento em quantidade suficiente para formar um filme na área que entra em contato com o paciente. Lave após o uso.
PARA ABRIR A BOLSA: Abra cuidadosamente a partir da área marcada.
PRECAUÇÕES ESPECIAIS: Precauções: Se o recipiente estiver danificado ou aberto, o Produto não é garantido.
CONTRA-INDICAÇÃO: Não há contra-indicação conhecida
SOBREDOSAGEM E EFEITOS COLATERAIS: Não há sintomas conhecidos para o uso de overdose.
SENSIBILIDADE À GLICERINA: A glicerina possui propriedades emolientes. Precauções Devem ser tomadas ao usar o gel em pessoas com sensibilidade à glicerina.
IDENTIFICAÇÃO: Transparente, solúvel em água, sem graxa e geléia.
APRESENTAÇÃO: Tubos que contenham: 42 gr, 50 gr, 82 gr, 113,4 gr, 100gr, 250gr, 1000gr
SAQUETAS QUE CONTENHAM: 2,5 gr, 3 gr, 3,5 gr, 4 gr, 4,5 gr, 5 gr, 10 gr
INSTRUÇÕES DE ARMAZENAMENTO: Armazenar entre 5-30 ° C
MANTENHA FORA DO ALCANCE DE CRIANÇAS

TRADEMARK / KLY

PROSPEKTÜS/IFU

Tarih: 23 / 02 / 2023

ÜRÜN KODU	: 150.06.05.0582		
ÜRÜN İSMİ	: KLY NON-STERIL ORTAK PROSPEKTUS - YENI ADRES - REV.10		
MALZEME CİNSİ	: I.HAMUR 70 GR		
GİRECEĞİ KUTU ÖLÇÜSÜ	: 135x40x30mm	KATLAMA	: OLACAK
RENK	: BLACK	ÖLÇÜ	: 285X120 MM

AÇIKLAMA / NOT

Turkuaz Sağlık Hizmetleri, Medikal, Temizlik Kimyasal Ürünler San. ve Tic. A.Ş.
Akçaburgaz Mah. Muhsin Yazıcıoğlu Cad. No:45/5 34522 Esenyurt / İstanbul / Türkiye
T +90 212 428 6848 Pbx **F** +90 212 428 6853 **info@**turkuazsaglik.com.tr / www.**turkuazsaglik**.com.tr

A T S E R T İ F İ K A

Üretim Kalite Güvence Sistemi

93/42/AT Tıbbi Cihazlar Direktifi Ek V

Firma Adı : Turkuaz Sağlık Hizmetleri Medikal Temizlik Kimyasal Ürünler San. ve Tic. A.Ş.

Firma Adresi : Yakuplu Mah. Birlik Cad. No:32/1 İç Kapı No:1 Beylikdüzü İSTANBUL / TÜRKİYE

İlgili Yönetmelikler ve Ekler : MDD 93/42/AT Tıbbi Cihazlar Yönetmeliği - Ek V

Ürünler : Steril Buğu Önleyici Solusyonu - Sınıf IIa
Steril Obstetrik Jel - Sınıf IIa
Steril Olmayan Kayganlaştırıcı Jel - Sınıf IIa
Steril Kayganlaştırıcı Jel - Sınıf IIa
Steril Olmayan Parabensiz Kayganlaştırıcı Jel - Sınıf IIa

GMDN : 45225, 60796, 33587, 60796, 34131

Sertifika Numarası	: M.2018.106.9536
Rapor Numarası	: MD.3561.IB
İlk Belgelendirme Denetimi	: 31.01.2018
Tescil Tarihi	: 13.04.2018
Revizyon Tarihi/No	: 03.05.2018/01
Geçerlilik Tarihi	: 12.04.2023

UDEM Uluslararası Belgelendirme Denetim Eğitim Merkezi San. ve Tic. A.Ş.

UDEM, Listeli ürünlerin 93/42/AT direktifi Ek V, gerekliliklerinin karşıladığını beyan eder. Yukarıda adı geçen üretici Kalite Güvence Sistemi uyguladığını ve Ek V madde 4'e göre periyodik gözaetim denetimleri ile sürekliliğini sağlayacağını beyan eder. Sınıf III olarak piyasaya arz edilecek ürünler için Ek II madde 4'e göre AT Tasarım İnceleme sertifikası gereklidir. Bu belgenin mülkiyet hakkı UDEM Uluslararası Belgelendirme Denetim Eğitim San. ve Tic. A.Ş.'ye aittir ve istenildiğinde iade edilmelidir. Yukarıda adı geçen firma ve UDEM bu belgenin bir kopyasını Tescil tarihinden itibaren 5 yıl süre ile muhafaza etmelidir. CE Markalamanın kullanımı üretici beyanı ile firma sorumluluğundadır. Adı geçen firma onaylanmış ürün ile ilgili bütün değişiklikleri UDEM'e bildirmek zorundadır. UDEM bu belgenin geçerliliğini yenilemezse adı geçen firma söz konusu ürünün piyasaya arzını durduracaktır. Belgenin geçerliliğini www.udem.com.tr internet sayfasından kontrol edebilirsiniz.

CE 2292

Adres: Mutlukent Mahallesi 2073 Sokak (Eski 93 Sokak) No:10 Çankaya – Ankara – TÜRKİYE
Tel: +90 312 443 03 90 **Faks:** +90 312 443 03 76
E-posta: info@udemltd.com.tr www.udem.com.tr

E C C E R T I F I C A T E

Production Quality Assurance for Medical Devices Directive 93/42/EEC Annex V

Company Name	: Turkuaz Sağlık Hizmetleri Medikal Temizlik Kimyasal Ürünler San. ve Tic. A.Ş.
Company Address	: Yakuplu Mah. Birlik Cad. No:32/1 İç Kapı No:1 Beylikdüzü ISTANBUL / TURKEY
Related Directives and Annex	: MDD 93/42/EEC Medical Devices Directive - Annex V
Product	: Sterile Antifog Solution - Class IIa Sterile Obstetric Gel - Class IIa Non-sterile Lubricant Gel - Class IIa Sterile Lubricant Gel - Class IIa Non-sterile Paraben-Free Lubricant Gel - Class IIa
GMDN	: 45225, 60796, 33587, 60796, 34131

Certificate Number	: M.2018.106.9536
Report Number	: MD.3561.IB
Initial Assessment Date	: 31.01.2018
Registration Date	: 13.04.2018
Revision Date /No	: 03.05.2018/01
Expiry Date	: 12.04.2023

UDEM International Certification Auditing Training Centre Industry and Trade Inc. Co.

UDEM hereby declares that the requirements of Annex V, of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance audits, defined by Annex V, section 4 of the forementioned directive. According to Annex II, section 4 an EC design- examination certificate is required for placing the Class III devices on the market. This certificate remains as the property of UDEM International Certification Auditing Training Centre Industry and Trade Inc. Co. to whom it must be returned upon request. The above named company and UDEM must keep a copy of this certificate for 5 years from the registration of the certificate. Usage of the CE mark is under the responsibility of the manufacturer with the completion of EC Declaration of Conformity. The above mentioned company must notify all changes related with the approved product to UDEM. If UDEM will not renew the expiry date of this certificate in question, the mentioned company should stop placing the product on the market. The currency of the certificate can be checked through www.udem.com. tr.

CE 2292

Addrres: Mutlukent Mahallesi 2073 Sokak (Eski 93 Sokak) No:10 Çankaya – Ankara – TURKEY
Phone: +90 0312 443 03 90 **Fax:** +90 0312 443 03 76
E-mail: info@udemltd.com.tr www.udem.com.tr

UDEM Adriatic d.o.o.
Radnička cesta 54/R3
10000 Zagreb, CROATIA

2023/05/15

Turkuaz Sağlık Hizmetleri Medikal Temizlik
Kimyasal Ürünler Sanayi ve Ticaret A.Ş.
Akçaburgaz Mah. Muhsin Yazıcıoğlu Cad.
No: 45/5 Esenyurt, İstanbul, Türkiye

NOTIFIED BODY CONFIRMATION LETTER

Reference: 2023.MDR.1060.NBCL.0005

To whom it may concern,

Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation EU 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices.

This letter confirms that, UDEM ADRIATIC D.O.O., a Notified Body (NB) designated under Regulation (EU) 2017/745 (MDR) and identified by the number 2696 on NANDO, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR (on the date of 2022/11/16) and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR (on the date of 2022/11/16) with the following manufacturer:

Turkuaz Sağlık Hizmetleri Medikal Temizlik

Kimyasal Ürünler Sanayi ve Ticaret A.Ş.

Akçaburgaz Mah. Muhsin Yazıcıoğlu Cad.

No:45/5 Esenyurt, İstanbul, Türkiye

SRN Number (if available): TR-MF-000015402

The devices covered by the formal application and the written agreement mentioned above are identified in the Tables below. Table 1 identifies the devices for which an MDR application has been received, written agreement concluded and for which UDEM Adriatic d.o.o. is also responsible for appropriate surveillance of the corresponding devices under Directive 93/42/EEC (MDD). Table 2 identifies the devices for which an MDR application has been received and a

written agreement concluded, but UDEM Adriatic d.o.o. has not yet taken the responsibility for appropriate surveillance of the corresponding devices under MDD.

In the case of devices covered by certificates issued under MDD that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD certificate expiry; or provided evidence that a competent authority of a Member State had granted a derogation or exemption from the applicable conformity assessment procedure in accordance with Article 59(1) of MDR or Article 97(1) of the MDR respectively, by the 20 March 2023 for the relevant devices.

The transition timelines that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120(3c) of MDR (as amended by (EU) 2023/607), are shown below:

- 26 May 2026 for Class III custom-made implantable devices
- 31 December 2027 for Class III devices and Class IIb implantable devices excluding Well-established technologies (WET - sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors)
- 31 December 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function
- 31 December 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments)

On behalf of UDEM Adriatic d.o.o.

Zekeriya AYTAÇ

General Manager

UDEM Adriatic d.o.o.
UDEM OIB:50373079784
Radnička cesta 54/R3, Green Gold Centar,IV.kat,Zagreb
Tel:(1)4819601 Fax: (1)4819434
www.udemadriatic.com

Table 1: Devices covered by this letter and for which UDEM Adriatic d.o.o. is also responsible for appropriate surveillance of the corresponding devices under Directive 93/42/EEC (MDD)

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD device	MDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
N/A	N/A	N/A	N/A

Table 2: Devices covered by this letter and for which UDEM Adriatic d.o.o. is NOT responsible for appropriate surveillance of the corresponding devices under Directive 93/42/EEC (MDD)

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD device	MDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Obstetric Gel	Class IIb excluding Class IIb implantable non-WET	N/A	**Certificate 1:** Production Quality Assurance Certificate No: M.2018.106. 9536 UDEM Uluslararası Belgelendirme Denetim Egitim Merkezi San. ve Tic. A.Ş. (NB2292)
Konix Lido Sterile Catheter Gel (Chlorhexidine Gluconate)	Class III	N/A	**Certificate 1:** Full Quality Assurance System Certificate No: M.2021.106. 14604 UDEM Uluslararası Belgelendirme Denetim Egitim Merkezi San. ve Tic. A.Ş. (NB2292) **Certificate 2:** EC Design Examination Certificate No: M.2021.106. 14604-1 UDEM Uluslararası Belgelendirme Denetim Egitim Merkezi San. ve Tic. A.Ş. (NB2292)

UDEM Adriatic d.o.o.
UDEM OIB:5037[illegible]784
Radnička cesta 54/R3, Green Gold Centar,IV.kat,Zagreb
Tel.(1)4819601 Fax: (1)4819434
www.udemadriatic.com

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD device	MDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Konix Lido Sterile Catheter Gel with Lidocain	Class III	N/A	**Certificate 1:** Full Quality Assurance System Certificate No: M.2021.106. 14603 UDEM Uluslararası Belgelendirme Denetim Egitim Merkezi San. ve Tic. A.Ş. (NB2292) **Certificate 2:** EC Design Examination Certificate No: M.2021.106. 14603-1 UDEM Uluslararası Belgelendirme Denetim Egitim Merkezi San. ve Tic. A.Ş. (NB2292)
Konix Lido+ Chlorhexidine Sterile Catheter Gel, with Lidocain	Class III	N/A	**Certificate 1:** Full Quality Assurance System Certificate No: M.2020.106. 13505 UDEM Uluslararası Belgelendirme Denetim Egitim Merkezi San. ve Tic. A.Ş. (NB2292) **Certificate 2:** EC Design Examination Certificate No: M.2020.106. 13505-1 UDEM Uluslararası Belgelendirme Denetim Egitim Merkezi San. ve Tic. A.Ş. (NB2292)
Aromatic and Steril /Nonsteril Nonaromatic Lubricant Gels (In case of Lubricants specifically intended for use together with medical devices (e.g. for gloves, endoscopes, condoms))	Class IIb excluding Class IIb implantable non-WET	N/A	**Certificate 1:** Production Quality Assurance Certificate No: M.2018.106. 10376 UDEM Uluslararası Belgelendirme Denetim Egitim Merkezi San. ve Tic. A.Ş. (NB2292)

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD device	MDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
			Certificate 2: Production Quality Assurance Certificate No: M.2018.106. 9536 UDEM Uluslararası Belgelendirme Denetim Egitim Merkezi San. ve Tic. A.Ş. (NB2292) **Certificate 3:** Production Quality Assurance Certificate No: M.2021.106. 14521 UDEM Uluslararası Belgelendirme Denetim Egitim Merkezi San. ve Tic. A.Ş. (NB2292) **Certificate 4:** Production Quality Assurance Certificate No: 0425-MED-004476-00 ICIM S.p.A. (NB0425)
Sterile Ultrasound Gel (invavize usage& body surface)	Class IIb excluding Class IIb implantable non-WET	N/A	**Certificate 1:** Full Quality Assurance System Certificate No: M.2018.106. 9377 UDEM Uluslararası Belgelendirme Denetim Egitim Merkezi San. ve Tic. A.Ş. (NB2292)
Antifog Solution	Class IIb excluding Class IIb implantable non-WET	N/A	**Certificate 1:** Production Quality Assurance Certificate No: M.2018.106. 9536 UDEM Uluslararası Belgelendirme Denetim Egitim Merkezi San. ve Tic. A.Ş. (NB2292)

UDEM Adriatic d.o.o.
UDEM OIB:5037307976
Radnička cesta 54/R3, Green Gold Centar, IV kat Zagreb
Tel:(1)4819601 Fax:(1)4819434
www.udemadriatic.com

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
2023/05/15	2023.MDR.1060.NBCL.0005	Initial issue

UDEM Adriatic d.o.o.
UDEM OIB:50373077764
Radnička cesta 54/R3, Green Gold Centar,IV.kat,Zagreb
Tel:(1) 4819601 Fax: (1) 4819434
www.udemadriatic.com

INTERNATIONAL CERTIFICATION

Certificate

TURKUAZ SAGLIK HIZMETLERI MEDIKAL TEMIZLIK KIMYASAL URUNLER SAN. VE TIC. A. S.

company,

AKCABURGAZ MAH. MUHSIN YAZICIOGLU CAD. NO: 45/5 POST CODE: 34522
ESENYURT/ISTANBUL/TURKIYE
in address,

MEDICAL DEVICES (DEVICE DISINFECTANT/BATH-X-RAY/ CLEANING SOLUTIONS, STERILE/NON-STERILE SOLUTIONS AND LUBRICANTS-AUXILIARY GELS, LICE/NIT/SMEAR SHAMPOO AND SPRAYS, WOUND-BURN CARE/TREATMENT PRODUCTS, HEAT TRANSFER PADS, IRRIGATION SOLUTIONS, NOSE WASH AND SPRAYS, STERILE/GLYCERIN WATER, SALINE FLUSH SYRINGE, PHYSIOLOGICAL SALINE SOLUTION AND POVIDONE-IOINE–BASED DISINFECTANT) PRODUCTS FOR SURGICAL HAND INSTRUMENTS, FOR THEIR DESIGN, PRODUCTION, PACKAGING, LABELING, STERILIZATION, STORAGE, SALES, MARKETING, IMPORT AND EXPORT

on scope,

ISO 13485:2016

Medical Devices-Quality Management System

Not Applicable: 7.5.3, 7.5.4, 7.5.9.2

Certificate No	: C-US-20245563	Certification Period	: 3 Years
Date of Certification	: 30.12.2020	Revision No	: 04
Date of Issue	: 17.12.2025	Revision Date	: 17.12.2025
Expiry Date	: 29.12.2026		

INTERNATIONAL CERTIFICATION TGS CERT ACCREDITED BODY

APPROVAL

MEMBER OF MULTILATERAL RECOGNITION ARRANGEMENT IAF

IAS ACCREDITED Management Systems Certification Body MSCB-139

The validity of the certificate depends on observance of the TGS rules. Certificate validity may be checked on www.tgscert.com

TGS INTERNATIONAL CERTIFICATION TECHNICAL CONTROL AND SURVEILLANCE SERVICES CO. LTD.
284 CHASE ROAD, A BLOCK 2ND FLOOR SUITE 341, LONDON, ENGLAND N14 6HF
Phone: +90 216 327 09 77(Pbx) Fax: +90 216 546 05 70
info@tgscert.com // www.tgscert.com

INTERNATIONAL CERTIFICATION

Certificate

TURKUAZ SAGLIK HIZMETLERI MEDIKAL TEMIZLIK KIMYASAL URUNLER SAN. VE TIC. A. S.

company,

AKCABURGAZ MAH. MUHSIN YAZICIOGLU CAD. NO: 45/5 POST CODE: 34522
ESENYURT/ISTANBUL/TURKIYE
in address,

MEDICAL DEVICES (DEVICE DISINFECTANT/BATH-X-RAY/ CLEANING SOLUTIONS, STERILE/NON-STERILE SOLUTIONS AND LUBRICANTS-AUXILIARY GELS, LICE/NIT/SMEAR SHAMPOO AND SPRAYS, WOUND-BURN CARE/TREATMENT PRODUCTS, HEAT TRANSFER PADS, IRRIGATION SOLUTIONS, NOSE WASH AND SPRAYS, STERILE/GLYCERIN WATER, SALINE FLUSH SYRINGE, PHYSIOLOGICAL SALINE SOLUTION, IN VITRO DIAGNOSTIC DEVICES (SAMPLE COLLECTION AND STORAGE DEVICES), COSMETIC AND DERMOCOSMETIC PRODUCTS (SHAMPOOS, CREAMS, SOLUTIONS AND SERUMS), BIOCIDAL PRODUCTS (ANTISEPTICS AND DISINFECTANTS), FOOD PRODUCTS (SUPPLEMENTS AND OTC), ANTISEPTIC AND BIOCIDAL INTRAVAGINAL SOLUTIONS, WIPES, POVIDONE-IOINE–BASED DISINFECTANT PRODUCTS FOR SURGICAL HAND INSTRUMENTS, FOR THEIR DESIGN, PRODUCTION, PACKAGING, LABELING, STERILIZATION, STORAGE, SALES, MARKETING, IMPORT AND EXPORT

on scope,

ISO 9001:2015

Quality Management System

Not Applicable: -
Is applicable.

Certificate No	: Q-US-20245563	Certification Period	: 3 Years
Date of Certification	: 30.12.2020	Revision No	: 03
Date of Issue	: 17.12.2025	Revision Date	: 17.12.2025
Expiry Date	: 29.12.2026	IAF Kod	: 3,12,23

APPROVAL

ACCREDITED
Management Systems
Certification Body
MSCB-139

The validity of the certificate depends on observance of the TGS rules. Certificate validity may be checked on www.tgscert.com

TGS INTERNATIONAL CERTIFICATION TECHNICAL CONTROL AND SURVEILLANCE SERVICES CO. LTD.
284 CHASE ROAD, A BLOCK 2ND FLOOR SUITE 341, LONDON, ENGLAND N14 6HF
Phone: +90 216 327 09 77(Pbx) Fax: +90 216 546 05 70
info@tgscert.com // www.tgscert.com