



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.

KLY® GLEITGEL



PRODUKTNAME: KLY® GLEITGEL
INHALT: Deionisiertes Wasser, natürliches Glycerin, MonopropylenGlykol, Hydroxyethyl Cellulose, Methylhydroxybenzoat, Zitronensäure
VERWENDUNGSZWECK: Endoskopie, Koloskopie, gynäkologische Untersuchungen, rektoskopische Anwendungen, bei Katheter-Verwendungen 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 schmierien 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



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 rectoscopias, 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 embalaje: Para usar abrir cuidadosamente en los lugares marcados.

PRECAUCIONES DE SEGURIDAD: Medidas de seguridad: Si la cubierta está abierta o embalaje está dañado, no hay garantía de producto.

EFFECTOS 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: Tube: 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 مزلق KLY®

اسم المنتج :

جل مزلق KLY®
معلومات عن المكونات:

ماء منزوع الأيونات ، جلسرين طبيعي ، جلايكول مونوبروبيلين ، هيدروكسي إيثيل السليلوز ، ميثيل هيدروكسي بنزو ، حمض الستريك.

الغرض من الاستخدام :

يتم استخدام التنظير ، تنظير القولون ، الفحوصات النسائية ، تطبيقات التنظير أيضا للتحق المهبلي في تطبيقات القسطرة .

طريقة الاستعمال:

فتح الأنبوب: افتح الغطاء عن طريق تدوير الغطاء التي تقع على الجزء العلوي من الأنبوب. وبعد ذلك تقليب الأنبوب وبمساعدة طرف مدبب في الداخل تضغط على قم الأنبوب وتقبب الأنبوب. استخدم كمية كافية من جل لوبريكنت لإنشاء طبقة على السطح بمساعدة قفاز أو أداة أخرى لاستخدامها في المرضى. وغسل بعد الاستعمال.
طريقة فتح الكيس: فتتح الكيس بعناية من الأماكن المميز.
احتياطات السلامة:

لا يوجد موانع معروفة لـ جل لوبريكنت KLY
الجرعة الزائدة والآثار الجانبية:

لم يتم العثور على أعراض إذا تم استخدام جرعة زائدة .
حساسية للغليسرين: يوفر الغليسرين بتزطيب البشرة. بما أن بعض أنواع البشرة حساسة للغليسرين ، يجب أخذ هذا التأثير بعين الاعتبار أثناء الاستخدام.

تعريف المنتج:

شفاف اللون ، قابلة للذوبان في الماء ، جل مزلق

أنواع مختلفة من التعبئة:

أنبوب: 42 غرام ،50غرام ، 82 ، 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 علبه ما بين درجات حرارية 5-30 درجة مئوية.

يقيه بعيدا عن متناول الأطفال.

معلومات حول المصنع والعلامة التجارية:

العلامة التجاريةKLY :

ГЕЛЬ ЛУБРИКАНТ KLY®



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. Неиспользуемые остатки, имеющие на наружной стороне крышки, прокалите 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.

СПОСОБ ПРИМЕНЕНИЯ: Откройте крышку на тюбике. После чего при помощи острого наконечника, имеющегося на наружной стороне крышки, прокалите 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 препарата 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. 3,5 г. 4. 4,5 г. 5 г. 10 г.

бутылка: 250мл.

Хранить в плотно закрытом тюбике или коробке при температуре 5-30 °С.

ХРАНИТЕ В МЕСТАХ, НЕДОСТУПНЫХ ДЕТЯМ.

KLY® ΓΚΕΛ ΛΥΠΑΝΣΗΣ



ΟΝΟΜΑΣΙΑ ΠΡΟΪΟΝΤΟΣ: KLY® ΓΚΕΛ ΛΥΠΑΝΣΗΣ
ΣΥΝΘΕΣΗ: Αποιονισμένο Νερό, Φυσική Γλυκερίνη, Μ ο ν ο π ρ ο π υ λ ε ν ο γ λ υ κ ο λ ή ρ , Υδροξυαιθυλοκυτταρίνη, Υδροξυβενζοϊκό Μεθύλιο, Κιτρικό Οξύ

ΠΡΟΒΛΕΠΟΜΕΝΗ ΧΡΗΣΗ: Αυτό το γκέλ χρησιμοποιείται για εφαρμογές ενδοσκόπησης, κολonosκόπησης, 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 Λίπανση 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 φακέλακι: 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.

ΑΝΑΓΩΡΪΣΗ: Διαφανής, υδατοδιαλυτό, χωρίς λιπαρά και ζέλ.

ΜΟΡΦΗ ΠΑΡΟΥΣΙΑΣΗΣ: Σαλήνες Περιέχουν καθώς: 42 γρ, 50 γρ, 82 γρ, 113,4 γρ, 100 γρ ή 250 γρ, 1000 γρ

Φακέλακι 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



ÜRÜN ADI: KLY® KAYGANLAŞTIRICI JEL

İÇERİK BİLGİSİ: Deionized water, Natural Glycerin, Monopropylen Glycol, Hydrox Ethyl Cellulose, Methyl Hydroxybenzoate, Citric Acid

KULLANIM AMACI: Endoskopi, kolonoskopi, jinekolojik muayeneler, rektoskopi uygulamaları, sonda uygulamalarında ayrıca vajinal lubrikasyonu 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: İşaretili yerden dikkatli bir şekilde açılarak kullanılır.

GÜVENLİK ÖNLEMLERİ: Güvenlik Önlemleri: Ambalajın kapağı açık veya hasarlı ise ürün garantisiz verilemez.

KONTRAENDİKASYON: KLY Lubricant Jeli'n bilinen bir kontraendikasyonu yoktur.

AŞIRI DOZ VE YAN ETKİLER: Aşırı dozda kullanılması halinde herhangi bir semptoma rastlanılmamıştır.

GLİSERİNE 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

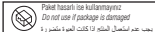
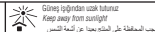
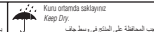


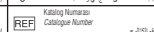
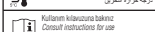




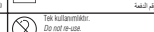
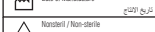

FARKLI AMBALAJ ŞEKİLERİ: Tüp: 42 g, 50g, 82 g, 113,4 g, 100 g, 250 g, 1000 g

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 ERIŞEMEYECEĞİ BİR YERDE SAKLAYINIZ.

MARKA/KLY

 <p>Do not use if packaging is damaged Do not use if the package is damaged بعد فتح التغليف إذا كانت العبوة مشددة</p>	 <p>Keep away from sunlight Bütün ışıklardan uzak tutunuz Bütün ışıklardan uzak tutunuz</p>	 <p>Keep Dry Kuru ortamda saklayınız Kuru Ortamda Saklayınız</p>
 <p>Storage Temperature Depolama Sıcaklığı Depolama Sıcaklığı</p>	 <p>Caution Dikkat Dikkat</p>	 <p>Country of Origin Ülke Ülke</p>
 <p>Consult instructions for use Kullanım talimatlarına bakınız Kullanım talimatlarına bakınız</p>	 <p>Manufacturer Ülke Ülke</p>	 <p>LOT "LOT" numbers Batch Code</p>
 <p>Date of Manufacture Üretim Tarihi Üretim Tarihi</p>	 <p>Expiration Date (Months/Year) Saklama Tarihi (ay/yıl) Exp. Date (Month/Year)</p>	 <p>Do not re-use. Tek kullanımlıdır. Do not re-use.</p>
 <p>Non-sterile Asteril değil Asteril değil</p>	 <p>Medical Device Tıbbi cihaz Tıbbi cihaz</p>	

Rev:10/23.02.2023

TRADEMARK / KLY

	
<p>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</p>	<p>Made in Turkey Discover the potential</p>

KLY® GEL LUBRIFIANT



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 reversez 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 émoullientes. 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

PROSPEKTÜS/IFU

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

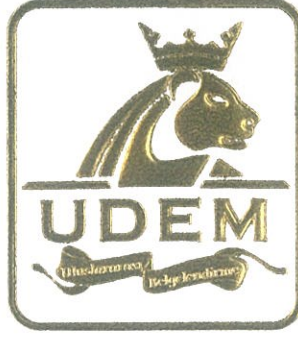
AÇIKLAMA / NOT	



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

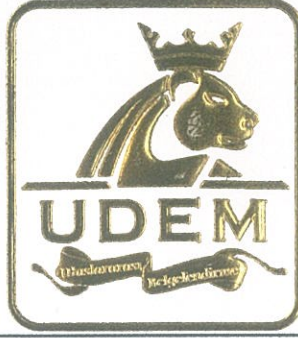

UDEM Uluslararası Belgelendirme
Denetim Eğitim Merkezi
San. ve Tic. A.Ş.

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 gözetim 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 Markalamasının 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



EC CERTIFICATE

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



Address: 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

UDEM Adriatic d.o.o.
Address: Radnička cesta 54/R3, Green Gold Centar, 10000 Zagreb
Phone: +385 (1) 4819 601 • **Fax:** +385 (1) 4819 434
E-mail: info@udemadriatic.com

**UDEM Adriatic d.o.o.**
UDEM OIB: 50373079784
Radnička cesta 54/R3, Green Gold Centar, IV.kat, Zagreb
Phone: +385 (1) 4819 601 Fax: (+385) 1 4819 434
www.udemadriatic.com

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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

UDEM Adriatic d.o.o.

Address: Radnička cesta 54/R3, Green Gold Centar, 10000 Zagreb

Phone: +385 (1) 4819 601 • Fax: +385 (1) 4819 434

E-mail: info@udemadriatic.com

UDFRM.235/01-08.05.2023/07.04.2023 Page 2 / 6

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	<p>Certificate 1: Production Quality Assurance Certificate No: M.2018.106. 9536</p> <p>UDEM Uluslararası Belgelendirme Denetim Egitim Merkezi San. ve Tic. A.Ş. (NB2292)</p>
Konix Lido Sterile Catheter Gel (Chlorhexidine Gluconate)	Class III	N/A	<p>Certificate 1: Full Quality Assurance System Certificate No: M.2021.106. 14604</p> <p>UDEM Uluslararası Belgelendirme Denetim Egitim Merkezi San. ve Tic. A.Ş. (NB2292)</p> <p>Certificate 2: EC Design Examination Certificate No: M.2021.106. 14604-1</p> <p>UDEM Uluslararası Belgelendirme Denetim Egitim Merkezi San. ve Tic. A.Ş. (NB2292)</p>

UDEM Adriatic d.o.o.

Address: Radnička cesta 54/R3, Green Gold Centar, 10000 Zagreb

Phone: +385 (1) 4819 601 • Fax: +385 (1) 4819 434

E-mail: info@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	<p>Certificate 1: Full Quality Assurance System Certificate No: M.2021.106. 14603</p> <p>UDEM Uluslararası Belgelendirme Denetim Egitim Merkezi San. ve Tic. A.Ş. (NB2292)</p> <p>Certificate 2: EC Design Examination Certificate No: M.2021.106. 14603-1</p> <p>UDEM Uluslararası Belgelendirme Denetim Egitim Merkezi San. ve Tic. A.Ş. (NB2292)</p>
Konix Lido+ Chlorhexidine Sterile Catheter Gel, with Lidocain	Class III	N/A	<p>Certificate 1: Full Quality Assurance System Certificate No: M.2020.106. 13505</p> <p>UDEM Uluslararası Belgelendirme Denetim Egitim Merkezi San. ve Tic. A.Ş. (NB2292)</p> <p>Certificate 2: EC Design Examination Certificate No: M.2020.106. 13505-1</p> <p>UDEM Uluslararası Belgelendirme Denetim Egitim Merkezi San. ve Tic. A.Ş. (NB2292)</p>
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	<p>Certificate 1: Production Quality Assurance Certificate No: M.2018.106. 10376</p> <p>UDEM Uluslararası Belgelendirme Denetim Egitim Merkezi San. ve Tic. A.Ş. (NB2292)</p>

UDEM Adriatic d.o.o.

Address: Radnička cesta 54/R3, Green Gold Centar, 10000 Zagreb

Phone: +385 (1) 4819 601 • Fax: +385 (1) 4819 434

E-mail: info@udemadriatic.com



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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
			<p>Certificate 2: Production Quality Assurance Certificate No: M.2018.106. 9536</p> <p>UDEM Uluslararası Belgelendirme Denetim Eğitim Merkezi San. ve Tic. A.Ş. (NB2292)</p> <p>Certificate 3: Production Quality Assurance Certificate No: M.2021.106. 14521</p> <p>UDEM Uluslararası Belgelendirme Denetim Eğitim Merkezi San. ve Tic. A.Ş. (NB2292)</p> <p>Certificate 4: Production Quality Assurance Certificate No: 0425-MED-004476-00</p> <p>ICIM S.p.A. (NB0425)</p>
Sterile Ultrasound Gel (invavize usage& body surface)	Class IIb excluding Class IIb implantable non-WET	N/A	<p>Certificate 1: Full Quality Assurance System Certificate No: M.2018.106. 9377</p> <p>UDEM Uluslararası Belgelendirme Denetim Eğitim Merkezi San. ve Tic. A.Ş. (NB2292)</p>
Antifog Solution	Class IIb excluding Class IIb implantable non-WET	N/A	<p>Certificate 1: Production Quality Assurance Certificate No: M.2018.106. 9536</p> <p>UDEM Uluslararası Belgelendirme Denetim Eğitim Merkezi San. ve Tic. A.Ş. (NB2292)</p>

UDEM Adriatic d.o.o.

Address: Radnička cesta 54/R3, Green Gold Centar, 10000 Zagreb

Phone: +385 (1) 4819 601 • **Fax:** +385 (1) 4819 434

E-mail: info@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: 50373070764
Radnička cesta 54/R3, Green Gold Centar, IV.kat.Zagreb
Tel: (1) 4819601 • Fax: (1) 4819434
www.udemadriatic.com

UDEM Adriatic d.o.o.


Address: Radnička cesta 54/R3, Green Gold Centar, 10000 Zagreb

Phone: +385 (1) 4819 601 • **Fax:** +385 (1) 4819 434

E-mail: info@udemadriatic.com

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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:	<table><thead><tr><th>Brand</th><th>Ref No</th><th>Version No</th><th>Model</th><th>Packaging</th><th>UDI-DI</th></tr></thead><tbody><tr><td>Lubrigima</td><td>29960</td><td>Y1015.105.0001</td><td>5 g</td><td>Plastic Bottle</td><td>8683229601597</td></tr></tbody></table>	Brand	Ref No	Version No	Model	Packaging	UDI-DI	Lubrigima	29960	Y1015.105.0001	5 g	Plastic Bottle	8683229601597
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
<p>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.</p> <p>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 A.Ş.' nin sorumluluğu altındadır.</p>	
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

TD-17-1.2.1_Rev.00_14.07.2025



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		



APPROVAL



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



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