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: *TELEPHONE:*	+902124286848
E-MAIL:	info@turkuazsaglik.com.tr
WEB SITE:	www.turkuazsaglik.com.tr
The Information of SRN Number:	TR-MF-000015402
MARKA: *TRADE MARK:*	KONIX
ÜRÜN ADI: *PRODUCTS:*	Steril Ultrason Jeli - 33269 Sterile Ultrasound Gel - 33269

Brand	Ref No	Version No	Model	Packaging	UDI-DI
KONIX	SUG-0001	Y1015.102.0001	20 ml	Sachet	8681715349695

GMDN KODU: *GMDN CODE:*	15321-Skin topical coupling gel A medium designed to be applied to a patient's unbroken skin surface (excludes the eye surface) to provide a coupling between an analytical or therapeutic device (e.g., ultrasound transducer, optical glucose monitoring system, transcutaneous electrical stimulator) and the patient, allowing for the emission and reception of energy/signals (e.g., electrical current, light) that pass through the skin during an examination or treatment. It is in the form of a fluid-like gel that may also assist in moving the parent device smoothly over the skin. It may be used by a healthcare professional in a clinical setting and layperson in the home. After application, this device cannot be reused.
SINIFLANDIRMA: *CLASSIFICATION:*	Annex IX of MDD 93/42/EEC Class IIa, Rule 5
UYGUNLUK DEĞERLENDİRME YOLU: *CONFORMITY ASSESSMENT ROUTE:*	MDD 93/42/EEC ANNEX II (section 4 excluded)(Bölüm 4 Hariç)
UYGULANABİLİR STANDARTLAR: *APPLICABLE STANDARDS:*	EN ISO 13485; EN ISO 14971 ; EN ISO 62366; EN 1041; EN ISO 14644-1; EN ISO 10993-1; EN ISO 10993-5; EN ISO 10993-10; EN ISO 15223-1; EN ISO 14698-1; ISO 16142-1; ISO/TR 20416; ISO 20417EN ISO 11607-1:2020/A1:2023, EN ISO 11607-2:2020/A1:2023, ISO 20417:2021,ISO 11140-1:2014, EN 17141:2020
TEKNİK DOSYA/TECHNICAL FILE: SAKLAMA ADRESİ/ RETAIN ADDRESS:	TD No/TF No: TD-05 Yukarıdaki adreste tutulmaktadır /Retained at te above address.

ONAYLANMIŞ KURULUŞ ADI VE NUMARASI/NOTIFIED BODY NAME &ID:	UDEM - 2292
CE BELGESİ SERTİFİKA NUMARASI/CE CERTIFICATE NUMBER:	M.2018.106.9377
CE BELGESİ BİTİŞ TARİHİ/CE CERTIFICATE EXPIRATION DATE:	06.03.23

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 A.Ş'nin sorumluluğu altındadır.

Yer, Place: *Istanbul* ***Tarih, Date:*** *11.07.2025*	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.
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