

AT UYGUNLUK BEYANI
EC DECLARATION OF CONFORMITY

COMPANY NAME:	Turkuaz Sağlık Hizmetleri Medikal Temizlik Kimyasal Ürünler Sanayi ve Ticaret A.Ş.
ADDRESS:	Akçaburgaz Mh. Muhsin Yazıcıoğlu Cd. No:45/5 34522 ESENYURT İSTANBUL-TÜRKİYE
TELEPHONE:	+902124286848
FAX:	+902124286853
E-MAIL:	info@turkuazsaglik.com.tr
PRODUCTS:	Non-Sterile Lubricant Jelly
TRADE MARK:	Gyneas
PRODUCT VOLUMES AND REF CODE:	250 ml 71436
GMDN CODE:	33587
CLASSIFICATION:	Annex IX of The MDD 93/42 EEC Class IIa, Rule 5
CONFORMITY ASSESSMENT ROUTE:	MDD 93/42/EEC ANNEX V
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 20417
TECHNICAL FILE: RETAIN ADDRESS: RESPONSIBLE PERSON:	TD No/TF No: TD-17 Retained at the above address. Resp. Person: Hanifi Karahan Bozkurt
NOTIFIED BODY NAME & ID:	UDEM - 2292
CE CERTIFICATE NUMBER:	M.2018.106.9536
CE CERTIFICATE EXPIRATION DATE:	12.04.2023

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.

Place: Istanbul Date: 28.09.2022	Signed by HANIFI KARAHAN BOZKURT R&D & 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 Tic Sic No: 271 055 40 10 Tic Sic No: 450836
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TD-17-1.2_Rev.05_22.10.2021

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

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