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ATAKAN DEDE-MİRAY MEDİKAL

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DEKLARASYON

DECLARATION OF CONFORMITY

ÜRETİCİ : *MANUFACTURER*	ATAKAN DEDE-MİRAY MEDİKAL	
ÜRÜN : *MEDICAL DEVICE*	**ÜRÜN ADI** *MEDICAL DEVICE NAME*	**SINIFI** *CLASS*
	OFTALMİK CERRAHİ İÇİN DENGELİ TUZ ÇÖZELTİSİ *BALANCED SALT SOLUTION FOR OPHTHALMIC SURGERY*	
	OCUSALT BALANCED SALT SOLUTION (DENGELİ TUZ ÇÖZELTİSİ) 500 cc	II A
	OCUSALT BALANCED SALT SOLUTION (DENGELİ TUZ ÇÖZELTİSİ) 1000 cc	II A
	OCUSALT BALANCED SALT SOLUTION (DENGELİ TUZ ÇÖZELTİSİ) 20 cc PP	II A
	OCUSALT BALANCED SALT SOLUTION (DENGELİ TUZ ÇÖZELTİSİ) 500 cc PP	II A
	GÖZ CERRAHİSİNDE KULLANILAN PERFLUORO DEKALİN *PERFLUORODECALIN FOR OPHTHALMIC SURGERY*	
	OCUDEKA DECALINE 5 ml	II A
	OCUDEKA DECALINE 7 ml	II A
	OCUDEKA DECALINE 10 ml	II A
	GÖZ CERRAHİSİNDE KULLANILAN SİLİKON YAĞI *SILICONE OIL FOR OPHTHALMIC SURGERY*	
	OCUSİL SILICONE OIL 1000 cst 10 ml	II B
	OCUSİL SILICONE OIL 1300 cst 10 ml	II B
	OCUSİL SILICONE OIL 2200 cst 10 ml	II B
	OCUSİL SILICONE OIL 5000 cst 10 ml	II B
	OCUSİL SILICONE OIL 5500 cst 10 ml	II B
	OCUSIL SILICONE OIL 5700 cst 10 ml	II B
	OCUSIL SILICONE OIL 1000 cst 10 ml (ENJ./SYRINGE)	II B
	OCUSIL SILICONE OIL 1300 cst 10 ml (ENJ./SYRINGE)	II B
	OCUSIL SILICONE OIL 2200 cst 10 ml (ENJ./SYRINGE)	II B
	OCUSIL SILICONE OIL 5000 cst 10 ml (ENJ./SYRINGE)	II B
	OCUSIL SILICONE OIL 5500 cst 10 ml (ENJ./SYRINGE)	II B
	OCUSIL SILICONE OIL 5700 cst 10 ml (ENJ./SYRINGE)	II B
	OCUSİL SILICONE OIL 1000 cst 15 ml	II B
	OCUSİL SILICONE OIL 1300 cst 15 ml	II B
	OCUSİL SILICONE OIL 2200 cst 15 ml	II B
	OCUSİL SILICONE OIL 5000 cst 15 ml	II B
	OCUSİL SILICONE OIL 5500 cst 15 ml	II B
	OCUSİL SILICONE OIL 5700 cst 15 ml	II B
	SODYUM HYALURONAT VİSKOELASTİK SOLÜSYON *SODIUM HYALURONATE VISCOELASTIC SOLUTION*	
	CROWN VİSC 1.0% (1,5 ml)	II B
	CROWN VİSC 1.4% (1,5 ml)	II B
	CROWN VISC 1.6% (1,5 ml)	II B
	CROWN VİSC 1.8% (1,5 ml)	II B

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	CROWN VİSC 3.0% (1,5 ml)	II B
	CROWN VİSC 1.0% (1,0 ml)	II B
	CROWN VİSC 1.4% (1,0 ml)	II B
	CROWN VISC 1.6% (1,0 ml)	II B
	CROWN VİSC 1.8% (1,0 ml)	II B
	CROWN VİSC 3.0% (1,0 ml)	II B
	CROWN VİSC 1.0% (1,6 ml)	II B
	CROWN VİSC 1.4% (1,6 ml)	II B
	CROWN VISC 1.6% (1,6 ml)	II B
	CROWN VİSC 1.8% (1,6 ml)	II B
	CROWN VİSC 3.0% (1,6 ml)	II B
	NEOCROWN COHESİVE 1.4% (1ml)	II B
	MEGACROWN 1.8% (1ml)	II B
	OCULOCROWN 2.0 % (1ml)	II B
	OCUVİSC SODIUM HYALURONATE %1.0 1.0 ml	II B
	OCUVİSC SODIUM HYALURONATE %1.2 1.0 ml	II B
	OCUVİSC SODIUM HYALURONATE %1.4 1.0 ml	II B
	OCUVİSC SODIUM HYALURONATE %1.5 1.0 ml	II B
	OCUVİSC SODIUM HYALURONATE %1.6 1.0 ml	II B
	OCUVİSC SODIUM HYALURONATE %1.8 1.0 ml	II B
	OCUVİSC SODIUM HYALURONATE %2.0 1.0 ml	II B
	OCUVİSC SODIUM HYALURONATE %2.2 1.0 ml	II B
	OCUVİSC SODIUM HYALURONATE %2.5 1.0 ml	II B
	OCUVİSC SODIUM HYALURONATE %3.0 1.0 ml	II B
	OCUVİSC SODIUM HYALURONATE %1.0 1.5 ml	II B
	OCUVİSC SODIUM HYALURONATE %1.2 1.5 ml	II B
	OCUVİSC SODIUM HYALURONATE %1.4 1.5 ml	II B
	OCUVİSC SODIUM HYALURONATE %1.5 1.5 ml	II B
	OCUVİSC SODIUM HYALURONATE %1.6 1.5 ml	II B
	OCUVİSC SODIUM HYALURONATE %1.8 1.5 ml	II B
	OCUVİSC SODIUM HYALURONATE %2.0 1.5 ml	II B
	OCUVİSC SODIUM HYALURONATE %2.2 1.5 ml	II B
	OCUVİSC SODIUM HYALURONATE %2.5 1.5 ml	II B
	OCUVİSC SODIUM HYALURONATE %3.0 1.5 ml	II B
	OCUVİSC SODIUM HYALURONATE %1.0 1.6 ml	II B
	OCUVİSC SODIUM HYALURONATE %1.2 1.6 ml	II B
	OCUVİSC SODIUM HYALURONATE %1.4 1.6 ml	II B
	OCUVİSC SODIUM HYALURONATE %1.5 1.6 ml	II B
	OCUVİSC SODIUM HYALURONATE %1.6 1.6 ml	II B
	OCUVİSC SODIUM HYALURONATE %1.8 1.6 ml	II B
	OCUVİSC SODIUM HYALURONATE %2.0 1.6 ml	II B
	OCUVİSC SODIUM HYALURONATE %2.2 1.6 ml	II B
	OCUVİSC SODIUM HYALURONATE %2.5 1.6 ml	II B
	OCUVİSC SODIUM HYALURONATE %3.0 1.6 ml	II B
	HİDROKSİPROPİL METİLSELÜLOZ VİSKOELASTİK SOLÜSYON *HYDROXYPROPYL METHYLCELLULOSE VISCOELASTIC SOLUTION*	
	CROWN GEL 2.0%	II B
	CROWN GEL 2.4%	II B
	CROWN GEL PLUS 2.0%	II B

	CROWN GEL PLUS 2.4%	II B
	GÖZ CERRAHİSİNDE KULLANILAN TRİPAN MAVİSİ *TRYPAN BLUE FOR OPHTHALMIC SURGERY*	
	OCUBLU-TRY TRYPAN BLUE % 0.02 (0,2 mg) 1 cc	II A
	OCUBLU-TRY TRYPAN BLUE % 0.04 (0,4 mg) 1 cc	II A
	OCUBLU-TRY TRYPAN BLUE % 0.06 (0,6 mg) 1 cc	II A
	OCUBLU-TRY TRYPAN BLUE % 0.02 (0,2 mg) 1 cc (ENJ./SYRINGE)	II A
	OCUBLU-TRY TRYPAN BLUE % 0.04 (0,4 mg) 1 cc (ENJ./SYRINGE)	II A
	OCUBLU-TRY TRYPAN BLUE % 0.06 (0,6 mg) 1 cc (ENJ./SYRINGE)	II A
	GÖZ CERRAHİSİNDE KULLANILAN ILM/ERM MAVİSİ *ILM/ERM BLUE FOR OPHTHALMIC SURGERY*	
	OCUBLU ILM BLUE 1 ML	II A
	OCUBLU ILM BLUE 1 ML (ENJ./SYRINGE)	II A
	OCUBLU ILM/ERM BLUE 1 ML	II A
	OCUBLU ILM/ERM BLUE 1 ML (ENJ./SYRINGE)	II A
	EKLEM İÇİ ENJEKSİYON *INTRA-ARTICULAR INJECTION*	
	CROWNFLEX Classic 20,0 mg Intra-articular Injection 2 ml	III
	CROWNFLEX Classic Plus 32,0 mg Intra-articular Injection 2 ml	III
	CROWNFLEX Ultra 40,0 mg Intra-articular Injection 2 ml	III
	CROWNFLEX Ultra Plus 60,0 mg Intra-articular Injection 2 ml	III
	SİLİKON VERME VE ÇIKARTMA SETİ *SILICONE INJECTION AND EXTRACTION SYSTEM*	
	VFE-1 OCUSİL VİSKOZ SIVI ASPİRASYON KİTİ 23 G (Disposable Viscous Fluid Extraction)	II A
	VFE-2 OCUSİL VİSKOZ SIVI ASPİRASYON KİTİ 25 G (Disposable Viscous Fluid Extraction)	II A
	VFI-1 OCUSİL VİSKOZ SIVI ENJEKSİYON VE ASPİRASYON KİTİ DORC-ALCON (Disposable Viscous Fluid Injection&Extraction)	II A
	VFI-2 OCUSİL VİSKOZ SIVI ENJEKSİYON VE ASPİRASYON KİTİ OERTLI (Disposable Viscous Fluid Injection&Extraction)	II A
	VFI-3 OCUSİL VİSKOZ SIVI ENJEKSİYON VE ASPİRASYON KİTİ BAUSCH&LOMB (Disposable Viscous Fluid Injection&Extraction)	II A
	VFI-4 OCUSİL VİSKOZ SIVI ENJEKSİYON VE ASPİRASYON KİTİ DORC(HARMONY) (Disposable Viscous Fluid Injection&Extraction)	II A
	OFTALMİK SOLÜSYON *OPHTHALMIC SOLUTION*	
	OCUSİL Prosthetic Eye Care Solution 15 ml Silicone oil – Lubricant for prosthetic eyes *(OCUSİL Protez Göz Bakım Solüsyonu 15 ml* *Silikon yağı – Protez gözler için yağlayıcı)*	II A
	HİDROKSİPROPİL METİL SELÜLOZ VİSKOELASTİK SOLÜSYON *HYDROXYPROPYL METHYL CELLULOSE VISCOELASTIC SOLUTION*	
	HpmcGel 2.0% Gonioscopy examination contact fluid 15 ml *(Gonyoskopi muayenesi temas sıvısı 15 ml)*	II A
	STERİL KAYGANLAŞTIRICI GÖZ DAMLASI *STERILE LUBRICANT EYE DROP*	
	Ocufull Fresh	II B
	Ocufull Fresh Plus	II B

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ADRES BİLGİLERİ *ADDRESS INFORMATION*	ÇALI MAH.14.(410) SOKAK NO:14B NİLÜFER / BURSA
TELEFON/ FAKS *TELEPHONE /FAX*	0224 441 33 34 / 0224 443 70 06
DEKLARASYON YAYIN TARİHİ/ YERİ *DECLARATION PUBLISHING DATE/ PLACE*	19.03.2012 ATAKAN DEDE-MİRAY MEDİKAL
REVİZYON TARİHİ ***REVISION DATE***	12.05.2021
GEÇERLİLİK TARİHİ: ***EXPIRY DATE***	26.05.2024
UYGUNLUK DEĞERLENDİRMESİ *CONFORMITY ASSESSMENT* Ürünlerimizin 93 / 42 / EEC TIBBİ CİHAZ YÖNETMELİĞİ' nin bütün hükümlerine (Ek 2'nin Tam Kalite Güvence Sistemine)uygun olduğunu beyan ederiz. Kanıt niteliğindeki tüm dökümanlar kalite güvence birimimizde tutulmaktadır. *We declare that our products satisfy the requirements of the European Directive 93/42/EEC and conform to all the provisions of European Directive 93/42/EEC (Full Quality Assurance System of Annex 2).*	
ONAYLANAN KURULUŞ *APPROVED COMPANY*	ATAKAN DEDE-MİRAY MEDİKAL
ONAYLAYAN KURULUŞ/ *NOTIFIED BODY* **ADRES/** *ADDRESS*	SZUTEST Uygunluk Değerlendirme A.Ş. Tatlısu Mahallesi, Akif İnan Sk. No:1, 34774 Ümraniye/İstanbul/ TÜRKİYE
ONAYLAYAN KURULUŞUN KİMLİK NUMARASI : *NOTIFIED BODY ID NO*	2195
CE SERTİFİKA NUMARASI: *CE CERTIFICATE NO*	2195-MED-1207901
UYGULANAN STANDARTLAR/ *APPLIED STANDARTS* ISO 13485:2016 / TS EN 1041+A1:2014 / TS EN 556-1:2009 / TS EN ISO 11138-3:2010 / EN ISO 10993-1:2014 / EN ISO 10993-1-AC:2014 / EN ISO 10993-13:2013 / EN ISO 10993-18:2010 / TS EN ISO 10993-5:2010 / TS EN ISO 10993-10:2014 / TS EN ISO 17665-1:2006 / TS EN ISO 11737-1: 2018 / TS EN ISO 11737-2:2010 / TSE EN ISO 14644-1:2016 / TS EN ISO 14644-2:2016 / TS EN ISO 14644-3:2019 / TS EN ISO 14644-4:2006 / TS EN ISO 9001:2015 / TS EN ISO 14971:2013 / TS EN 62366-1-AC:2016 / TS EN ISO 15223-1:2016 / TS EN ISO 15798:2014 / TS EN ISO 11607-1 :2017 / TS EN ISO 11607-2 :2017 / TS EN ISO 16671:2015 / Avrupa Farmakopesi (EP 10TH EDITION) / MEDDEV 2.12-1 Rev.8:01.2013 / MEDDEV.2.7.1 Rev.4:06.2016	
GMDN KODLARI *GMDN CODES*	37207: İrigasyon (yıkama) sıvısı (BSS) *(Irrigation fluid (BSS))* 35907: Aköz/vitröz hümör replasman ortamı *(Aqueous / vitreous humor replacement medium)* 45180: Göz boyası *(Eye dye)* 44757: Sinoviyal sıvı takviye maddesi *(Synovial fluid supplement)* 46840: Oftalmik kanülasyon seti, tek kullanımlık *(Ophthalmic cannulation set, single-use)* 44237: Lubrikant, Göz *(Lubricant, Eye)*
UNSPC KODLARI *UNSPC CODES*	42293504/ Göz irigasyon (yıkama) veya aspirasyon malzemeleri veya aksesuvarları (BSS) *(Eye irrigation or aspiration materials or accessories (BSS))* 42295126 / Göz cerrahisi için vitreoretinal fragmotom cerrahisi donanımı veya aksesuvarları *(Vitreoretinal fragmotomy equipments or accessories for ophthalmic surgery)* 42294528 / Viskoelastik ajan veya visko-cerrahi cihaz *(Viscoelastic agent or visco-surgical device)* 42142600 / Enjektörler ve aksesuarları *(Syringes and accessories)* 42294500 / Göz uzmanlık aletleri ve ilgili ürünler *(Eye specialist tools and related products)* 51241139 / Steril silikon yağı *(Sterile silicone oil)* 51171643/ Metilselüloz *(Methylcellulose)* 51241120/ Suni gözyaşı *(Artificial tears)*

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- Direktif 93/42/EEC Ek I Bölüm 7.4'de belirtilen ve 2001/83/EEC yönetmeliğinin 1 maddesinde belirtildiği gibi bir tıbbi cihazın parçası olmadığını,
- Avrupa Parlamentosu ve Konsey Direktifi 722/2012/EC gereğince hayvansal kökenli dokular,
- Avrupa Parlamentosu ve Konsey Direktifi 2000/70/EC, 2007/47/EC ve 2001/83/EC gereğince insan kanı ve ilaç bileşeni ihtiva etmediğini,
- Avrupa Parlamentosu ve Konseyinin 1272/2008/EC direktiflerine uygun olarak fitalat,
-2006/122/EC sayılı direktife uygun olarak PFOS (perfluoroctan sulfonates) içermediğini garanti ve beyan ederiz.

-We declare that our medical devices are not the part of a medical device as specified in article 1 of the Directive 2001/83/EEC and European Directive 93/42/EEC Annex I, Part 7.4.
-We also declare and guarantee that they are not included,
- Animal originated tissues according to the rules of European Parliament and Council Directive 722/2012/EC,
- Human blood and drug according to the rules of European Parliament and Council Directive 2000/70/EC, 2007/47/EC and 2001/83/EC
- Phthalate according to 1272/2008/EC Directive,
- PFOS (perfluoroctansulfonates) according to Directive 2006/122/EC.

İMZA *SIGNATURE*	

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