

DEKLARASYON
DECLARATION OF CONFORMITY

ÜRETİCİ MANUFACTURER	:	ATAKAN DEDE-MİRAY MEDİKAL	
ÜRÜN MEDICAL DEVICE	:	ÜRÜN ADI MEDICAL DEVICE NAME	SİNİFİ 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
		OCUSİL SILICONE OIL 5700 cst 10 ml	II B
		OCUSİL SILICONE OIL 1000 cst 10 ml (ENJ./SYRINGE)	II B
		OCUSİL SILICONE OIL 1300 cst 10 ml (ENJ./SYRINGE)	II B
		OCUSİL SILICONE OIL 2200 cst 10 ml (ENJ./SYRINGE)	II B
		OCUSİL SILICONE OIL 5000 cst 10 ml (ENJ./SYRINGE)	II B
		OCUSİL SILICONE OIL 5500 cst 10 ml (ENJ./SYRINGE)	II B
		OCUSİL 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 VİSC 1.6% (1,5 ml)	II B	
	CROWN VİSC 1.8% (1,5 ml)	II B	

	CROWN VISC 3.0% (1,5 ml)	II B
	CROWN VISC 1.0% (1,0 ml)	II B
	CROWN VISC 1.4% (1,0 ml)	II B
	CROWN VISC 1.6% (1,0 ml)	II B
	CROWN VISC 1.8% (1,0 ml)	II B
	CROWN VISC 3.0% (1,0 ml)	II B
	CROWN VISC 1.0% (1,6 ml)	II B
	CROWN VISC 1.4% (1,6 ml)	II B
	CROWN VISC 1.6% (1,6 ml)	II B
	CROWN VISC 1.8% (1,6 ml)	II B
	CROWN VISC 3.0% (1,6 ml)	II B
	NEOCROWN COHESIVE 1.4% (1ml)	II B
	MEGACROWN 1.8% (1ml)	II B
	OCULOCROWN 2.0 % (1ml)	II B
	OCUVISC SODIUM HYALURONATE %1.0 1.0 ml	II B
	OCUVISC SODIUM HYALURONATE %1.2 1.0 ml	II B
	OCUVISC SODIUM HYALURONATE %1.4 1.0 ml	II B
	OCUVISC SODIUM HYALURONATE %1.5 1.0 ml	II B
	OCUVISC SODIUM HYALURONATE %1.6 1.0 ml	II B
	OCUVISC SODIUM HYALURONATE %1.8 1.0 ml	II B
	OCUVISC SODIUM HYALURONATE %2.0 1.0 ml	II B
	OCUVISC SODIUM HYALURONATE %2.2 1.0 ml	II B
	OCUVISC SODIUM HYALURONATE %2.5 1.0 ml	II B
	OCUVISC SODIUM HYALURONATE %3.0 1.0 ml	II B
	OCUVISC SODIUM HYALURONATE %1.0 1.5 ml	II B
	OCUVISC SODIUM HYALURONATE %1.2 1.5 ml	II B
	OCUVISC SODIUM HYALURONATE %1.4 1.5 ml	II B
	OCUVISC SODIUM HYALURONATE %1.5 1.5 ml	II B
	OCUVISC SODIUM HYALURONATE %1.6 1.5 ml	II B
	OCUVISC SODIUM HYALURONATE %1.8 1.5 ml	II B
	OCUVISC SODIUM HYALURONATE %2.0 1.5 ml	II B
	OCUVISC SODIUM HYALURONATE %2.2 1.5 ml	II B
	OCUVISC SODIUM HYALURONATE %2.5 1.5 ml	II B
	OCUVISC SODIUM HYALURONATE %3.0 1.5 ml	II B
	OCUVISC SODIUM HYALURONATE %1.0 1.6 ml	II B
	OCUVISC SODIUM HYALURONATE %1.2 1.6 ml	II B
	OCUVISC SODIUM HYALURONATE %1.4 1.6 ml	II B
	OCUVISC SODIUM HYALURONATE %1.5 1.6 ml	II B
	OCUVISC SODIUM HYALURONATE %1.6 1.6 ml	II B
	OCUVISC SODIUM HYALURONATE %1.8 1.6 ml	II B
	OCUVISC SODIUM HYALURONATE %2.0 1.6 ml	II B
	OCUVISC SODIUM HYALURONATE %2.2 1.6 ml	II B
	OCUVISC SODIUM HYALURONATE %2.5 1.6 ml	II B
	OCUVISC SODIUM HYALURONATE %3.0 1.6 ml	II B
	HİDROKSİPROPİL METİLSELÜLOZ VİSKOELASTİK SOLÜSYON <i>HYDROXYPROPYL METHYLCELLULOSE VISCOELASTIC SOLUTION</i>	
	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 <i>TRYPAN BLUE FOR OPHTHALMIC SURGERY</i>	
	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 <i>ILM/ERM BLUE FOR OPHTHALMIC SURGERY</i>	
	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 <i>INTRA-ARTICULAR INJECTION</i>	
	CROWN FLEX Classic 20,0 mg Intra-articular Injection 2 ml	III
	CROWN FLEX Classic Plus 32,0 mg Intra-articular Injection 2 ml	III
	CROWN FLEX Ultra 40,0 mg Intra-articular Injection 2 ml	III
	CROWN FLEX Ultra Plus 60,0 mg Intra-articular Injection 2 ml	III
	SİLİKON VERME VE ÇIKARTMA SETİ <i>SILICONE INJECTION AND EXTRACTION SYSTEM</i>	
	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 <i>OPHTHALMIC SOLUTION</i>	
	OCUSİL Prosthetic Eye Care Solution 5 ml Silicone oil – Lubricant for prosthetic eyes (OCUSİL Protez Göz Bakım Solüsyonu 5 ml Silikon yağı – Protez gözler için yağlayıcı)	II A
	HİDROKSİPROPİL METİL SELÜLOZ VİSKOELASTİK SOLÜSYON <i>HYDROXYPROPYL METHYL CELLULOSE VISCOELASTIC SOLUTION</i>	
	HpmcGel 2.0% Gonioscopy examination contact fluid 10 ml (Gonyoskopi muayenesi temas sıvısı 10 ml)	II A
ADRES BİLGİLERİ <i>ADDRESS INFORMATION</i>	ÇALI MAH.14.(410) SOK.NO:14B NİLÜFER / BURSA	
TELEFON/ FAKS <i>TELEPHONE /FAX</i>	0224 441 33 34 / 0224 443 70 06	

DEKLARASYON YAYIN TARİHİ/ YERİ <i>DECLARATION PUBLISHING DATE/ PLACE</i>	19.03.2012 ATAKAN DEDE-MİRAY MEDİKAL
REVİZYON TARİHİ <i>REVISION DATE</i>	31.01.2020
GEÇERLİLİK TARİHİ: <i>EXPIRY DATE</i>	26.05.2024
UYGUNLUK DEĞERLENDİRMESİ <i>CONFORMITY ASSESSMENT</i> 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. <i>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).</i>	
ONAYLANAN KURULUŞ <i>APPROVED COMPANY</i>	ATAKAN DEDE-MİRAY MEDİKAL
ONAYLAYAN KURULUŞ/ NOTIFIED BODY <i>ADRES/ ADDRESS</i>	SZUTEST Uygunluk Değerlendirme A.Ş. Tatlısu Mahallesi, Akif İnan Sk. No:1, 34774 Ümraniye/İstanbul/ TÜRKİYE
ONAYLAYAN KURULUŞUN KİMLİK NUMARASI : <i>NOTIFIED BODY ID NO</i>	2195
CE SERTİFİKA NUMARASI: <i>CE CERTIFICATE NO</i>	2195-MED-1207901
UYGULANAN STANDARTLAR/ APPLIED STANDARDS 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-AC:2010 / TS EN ISO 11737-2:2010 / TSE EN ISO 14644-1:2016 / TS EN ISO 14644-2:2016 / TS EN ISO 14644-3:2006 / 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-A1:2014 / TS EN ISO 11607-2-A1:2014 / Avrupa Farmakopesi (EP 2005, 2007 / EP 8TH EDITION) / USP 34 / MEDDEV 2.12-1 Rev.8:01.2013 / MEDDEV 2.7-1- Rev.4:06.2016 / TS EN 980: 13.01.2011	
GMDN KODLARI <i>GMDN CODES</i>	37207: İrigasyon (yıkama) sıvısı (BSS) (<i>Irrigation fluid (BSS)</i>) 35907: Aköz/vitröz hümmör replasman ortamı (<i>Aqueous / vitreous humor replacement medium</i>) 45180: Göz boyası (<i>Eye dye</i>) 44757: Sinoviyal sıvı takviye maddesi (<i>Synovial fluid supplement</i>) 46840: Oftalmik kanülasyon seti, tek kullanımlık (<i>Ophthalmic cannulation set, single-use</i>)
UNSPC KODLARI <i>UNSPC CODES</i>	42293504: Göz irigasyon (yıkama) veya aspirasyon malzemeleri veya aksesuarları (BSS) (<i>Eye irrigation or aspiration materials or accessories (BSS)</i>) 42295126 / Göz cerrahisi için vitreoretinal fragmotom cerrahisi donanımı veya aksesuarları (<i>Vitreoretinal fragmotomy equipments or accessories for ophthalmic surgery</i>) 42294528 / Viskoelastik ajan veya visko-cerrahi cihaz (<i>Viscoelastic agent or visco-surgical device</i>) 42142600 / Enjektörler ve aksesuarları (<i>Syringes and accessories</i>) 42294500 / Göz uzmanlık aletleri ve ilgili ürünler (<i>Eye specialist tools and related products</i>) 51241139 / Steril silikon yağı (<i>Sterile silicone oil</i>) 51171643/ Metilselüloz (<i>Methylcellulose</i>)
- 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 (perfluorooctan 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 (perfluorooctansulfonates) according to Directive 2006/122/EC.

İMZA
SIGNATURE

