

**DEKLARASYON**  
**DECLARATION OF CONFORMITY**

ÜRETİCİ MANUFACTURER	:	ATAKAN DEDE-MİRAY MEDİKAL	
ÜRÜN MEDICAL DEVICE	:	<b>ÜRÜN ADI</b> MEDICAL DEVICE NAME	<b>SINIFI</b> CLASS
		<b>OFTALMİK CERRAHİ İÇİN DENGELİ TUZ ÇÖZELTİSİ</b> 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
		<b>GÖZ CERRAHİSİNDE KULLANILAN PERFLUORO DEKALİN</b> PERFLUORODECALIN FOR OPHTHALMIC SURGERY	
		OCUDEKA DECALINE 5 ml	II A
		OCUDEKA DECALINE 7 ml	II A
		OCUDEKA DECALINE 10 ml	II A
		<b>GÖZ CERRAHİSİNDE KULLANILAN SİLİKON YAĞI</b> 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
		<b>SODYUM HYALURONAT VİSKOELASTİK SOLÜSYON</b> 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
	<b>HİDROKSİPROPİL METİLSELÜLOZ VİSKOELASTİK SOLÜSYON</b> <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
<b>GÖZ CERRAHİSİNDE KULLANILAN TRİPAN MAVİSİ</b> <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
<b>GÖZ CERRAHİSİNDE KULLANILAN ILM/ERM MAVİSİ</b> <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
<b>EKLEM İÇİ ENJEKSİYON</b> <i>INTRA-ARTICULAR INJECTION</i>	
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
<b>SİLİKON VERME VE ÇIKARTMA SETİ</b> <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
<b>OFTALMİK SOLÜSYON</b> <i>OPHTHALMIC SOLUTION</i>	
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
<b>HİDROKSİPROPİL METİL SELÜLOZ VİSKOELASTİK SOLÜSYON</b> <i>HYDROXYPROPYL METHYL CELLULOSE VISCOELASTIC SOLUTION</i>	
HpmcGel 2.0% Gonioscopy examination contact fluid 15 ml (Gonyoskopi muayenesi temas sıvısı 15 ml)	II A
<b>STERİL KAYGANLAŞTIRICI GÖZ DAMLASI</b> <i>STERILE LUBRICANT EYE DROP</i>	
Ocufull Fresh	II B
Ocufull Fresh Plus	II B

<b>ADRES BİLGİLERİ</b> ADDRESS INFORMATION	ÇALI MAH.14.(410) SOKAK NO:14B NİLÜFER / BURSA
<b>TELEFON/ FAKS</b> TELEPHONE /FAX	0224 441 33 34 / 0224 443 70 06
<b>DEKLARASYON YAYIN TARİHİ/ YERİ</b> DECLARATION PUBLISHING DATE/ PLACE	19.03.2012 ATAKAN DEDE-MİRAY MEDİKAL
<b>REVİZYON TARİHİ</b> REVISION DATE	12.05.2021
<b>GEÇERLİLİK TARİHİ:</b> EXPIRY DATE	26.05.2024
<b>UYGUNLUK DEĞERLENDİRMESİ</b> 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).	
<b>ONAYLANAN KURULUŞ</b> APPROVED COMPANY	ATAKAN DEDE-MİRAY MEDİKAL
<b>ONAYLAYAN KURULUŞ/ NOTIFIED BODY</b> ADRES/ ADDRESS	SZUTEST Uygunluk Değerlendirme A.Ş. Tatlısu Mahallesi, Akif İnan Sk. No:1, 34774 Ümraniye/İstanbul/ TÜRKİYE
<b>ONAYLAYAN KURULUŞUN KİMLİK NUMARASI :</b> NOTIFIED BODY ID NO	2195
<b>CE SERTİFİKA NUMARASI:</b> CE CERTIFICATE NO	2195-MED-1207901
<b>UYGULANAN STANDARTLAR/ APPLIED STANDARTS</b> 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	
<b>GMDN KODLARI</b> GMDN CODES	37207: İrigasyon (yıkama) sıvısı (BSS) (Irrigation fluid (BSS)) 35907: Aköz/vitröz hümmör 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)
<b>UNSPC KODLARI</b> UNSPC CODES	42293504/ Göz irigasyon (yıkama) veya aspirasyon malzemeleri veya aksesuarları (BSS) (Eye irrigation or aspiration materials or accessories (BSS)) 42295126 / Göz cerrahisi için vitreoretinal fragmotom cerrahisi donanımı veya aksesuarları (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)

- 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

