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ATAKAN DEDE-MİRAY MEDİKAL

Digitally signed by Bolea Petru
Date: 2020.07.17 17:28:40 EEST
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Location: Moldova

# DEKLARASYON

## *DECLARATION OF CONFORMITY*

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| **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**<br>*HYDROXYPROPYL METHYLCELLULOSE VISCOELASTIC SOLUTION* | |
| | CROWN GEL 2.0% | II B |
| | CROWN GEL 2.4% | II B |
| | CROWN GEL PLUS 2.0% | II B |

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| | CROWN GEL PLUS 2.4% | II B |
| | **GÖZ CERRAHİSİNDE KULLANILAN TRİPAN MAVİSİ**<br>*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**<br>*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**<br>*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**<br>*SILICONE INJECTION AND EXTRACTION SYSTEM* | |
| | VFE-1 OCUSİL VİSKOZ SIVI ASPİRASYON KİTİ 23 G<br>(Disposable Viscous Fluid Extraction) | II A |
| | VFE-2 OCUSİL VİSKOZ SIVI ASPİRASYON KİTİ 25 G<br>(Disposable Viscous Fluid Extraction) | II A |
| | VFI-1 OCUSİL VİSKOZ SIVI ENJEKSİYON VE ASPİRASYON KİTİ DORC-ALCON<br>(Disposable Viscous Fluid Injection&Extraction) | II A |
| | VFI-2 OCUSİL VİSKOZ SIVI ENJEKSİYON VE ASPİRASYON KİTİ OERTLI<br>(Disposable Viscous Fluid Injection&Extraction) | II A |
| | VFI-3 OCUSİL VİSKOZ SIVI ENJEKSİYON VE ASPİRASYON KİTİ BAUSCH&LOMB<br>(Disposable Viscous Fluid Injection&Extraction) | II A |
| | VFI-4 OCUSİL VİSKOZ SIVI ENJEKSİYON VE ASPİRASYON KİTİ DORC(HARMONY)<br>(Disposable Viscous Fluid Injection&Extraction) | II A |
| | **OFTALMİK SOLÜSYON**<br>*OPHTHALMIC SOLUTION* | |
| | OCUSİL Prosthetic Eye Care Solution 5 ml<br>Silicone oil – Lubricant for prosthetic eyes<br>*(OCUSİL Protez Göz Bakım Solüsyonu 5 ml*<br>*Silikon yağı – Protez gözler için yağlayıcı)* | II A |
| | **HİDROKSİPROPİL METİL SELÜLOZ VİSKOELASTİK SOLÜSYON**<br>*HYDROXYPROPYL METHYL CELLULOSE VISCOELASTIC SOLUTION* | |
| | HpmcGel 2.0%<br>Gonioscopy examination contact fluid 10 ml<br>*(Gonyoskopi muayenesi temas sıvısı 10 ml)* | II A |
| **ADRES BİLGİLERİ**<br>*ADDRESS INFORMATION* | ÇALI MAH.14.(410) SOK.NO:14B NİLÜFER / BURSA | |
| **TELEFON/ FAKS**<br>*TELEPHONE /FAX* | 0224 441 33 34 / 0224 443 70 06 | |

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| **DEKLARASYON YAYIN TARİHİ/ YERİ**<br>*DECLARATION PUBLISHING DATE/ PLACE* | 19.03.2012 ATAKAN DEDE-MİRAY MEDİKAL |
| **REVİZYON TARİHİ**<br>***REVISION DATE*** | 31.01.2020 |
| **GEÇERLİLİK TARİHİ:**<br>***EXPIRY DATE*** | 26.05.2024 |
| **UYGUNLUK DEĞERLENDİRMESİ**<br>*CONFORMITY ASSESSMENT*<br>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.<br>*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**<br>*APPROVED COMPANY* | ATAKAN DEDE-MİRAY MEDİKAL |
| **ONAYLAYAN KURULUŞ/** *NOTIFIED BODY*<br>**ADRES/** *ADDRESS* | SZUTEST Uygunluk Değerlendirme A.Ş.<br>Tatlısu Mahallesi, Akif İnan Sk. No:1, 34774 Ümraniye/İstanbul/ TÜRKİYE |
| **ONAYLAYAN KURULUŞUN KİMLİK NUMARASI :**<br>*NOTIFIED BODY ID NO* | 2195 |
| ***CE SERTİFİKA NUMARASI:***<br>*CE CERTIFICATE NO* | 2195-MED-1207901 |
| **UYGULANAN STANDARTLAR/** *APPLIED STANDARTS*<br>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**<br>*GMDN CODES* | 37207: İrigasyon (yıkama) sıvısı (BSS) *(Irrigation fluid (BSS))*<br>35907: Aköz/vitröz hümör replasman ortamı *(Aqueous / vitreous humor replacement medium)*<br>45180: Göz boyası *(Eye dye)*<br>44757: Sinoviyal sıvı takviye maddesi *(Synovial fluid supplement)*<br>46840: Oftalmik kanülasyon seti, tek kullanımlık *(Ophthalmic cannulation set, single-use)* |
| **UNSPC KODLARI**<br>*UNSPC CODES* | 42293504: Göz irigasyon (yıkama) veya aspirasyon malzemeleri veya aksesuvarları (BSS) *(Eye irrigation or aspiration materials or accessories (BSS))*<br>42295126 / Göz cerrahisi için vitreoretinal fragmotom cerrahisi donanımı veya aksesuvarları *(Vitreoretinal fragmotomy equipments or accessories for ophthalmic surgery)*<br>42294528 / Viskoelastik ajan veya visko-cerrahi cihaz *(Viscoelastic agent or visco-surgical device)*<br>42142600 / Enjektörler ve aksesuarları *(Syringes and accessories)*<br>42294500 / Göz uzmanlık aletleri ve ilgili ürünler *(Eye specialist tools and related products)*<br>51241139 / Steril silikon yağı *(Sterile silicone oil)*<br>51171643/ Metilselüloz *(Methylcellulose)* |

- 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.

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| *-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.*<br>*-We also declare and guarantee that they are not included,*<br>*- Animal originated tissues according to the rules of European Parliament and Council Directive 722/2012/EC,*<br>*- Human blood and drug according to the rules of European Parliament and Council Directive 2000/70/EC, 2007/47/EC and 2001/83/EC*<br>*- Phthalate according to 1272/2008/EC Directive,*<br>*- PFOS (perfluoroctansulfonates) according to Directive 2006/122/EC.* | |
| **İMZA**<br>*SIGNATURE* |  |

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