

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

|                         |                          |                                                                                                     |                        |
|-------------------------|--------------------------|-----------------------------------------------------------------------------------------------------|------------------------|
| ÜRETİCİ<br>MANUFACTURER | :                        | ATAKAN DEDE-MİRAY MEDİKAL                                                                           |                        |
| ÜRÜN<br>MEDICAL DEVICE  | :                        | <b>ÜRÜN ADI</b><br>MEDICAL DEVICE NAME                                                              | <b>SINIFI</b><br>CLASS |
|                         |                          | <b>OFTALMİK CERRAHİ İÇİN DENGELİ TUZ ÇÖZELTİSİ</b><br>BALANCED SALT SOLUTION FOR OPHTHALMIC SURGERY |                        |
|                         |                          | OCUSALT BALANCED SALT SOLUTION<br>(DENGELİ TUZ ÇÖZELTİSİ) 500 cc                                    | II A                   |
|                         |                          | OCUSALT BALANCED SALT SOLUTION<br>(DENGELİ TUZ ÇÖZELTİSİ) 1000 cc                                   | II A                   |
|                         |                          | OCUSALT BALANCED SALT SOLUTION<br>(DENGELİ TUZ ÇÖZELTİSİ) 20 cc PP                                  | II A                   |
|                         |                          | OCUSALT BALANCED SALT SOLUTION<br>(DENGELİ TUZ ÇÖZELTİSİ) 500 cc PP                                 | II A                   |
|                         |                          | <b>GÖZ CERRAHİSİNDE KULLANILAN PERFLUORO DEKALİN</b><br>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><br>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><br>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                                                                                                |                        |

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|  | 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><br><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 |

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| CROWN GEL PLUS 2.4%                                                                                                                                                                   | II B |
| <b>GÖZ CERRAHİSİNDE KULLANILAN TRİPAN MAVİSİ</b><br><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><br><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><br><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  |
| <b>SİLİKON VERME VE ÇIKARTMA SETİ</b><br><i>SILICONE INJECTION AND EXTRACTION SYSTEM</i>                                                                                              |      |
| 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 |
| <b>OFTALMİK SOLÜSYON</b><br><i>OPHTHALMIC SOLUTION</i>                                                                                                                                |      |
| OCUSİL Prosthetic Eye Care Solution 15 ml<br>Silicone oil – Lubricant for prosthetic eyes<br>(OCUSİL Protez Göz Bakım Solüsyonu 15 ml<br>Silikon yağı – Protez gözler için yağlayıcı) | II A |
| <b>HİDROKSİPROPİL METİL SELÜLOZ VİSKOELASTİK SOLÜSYON</b><br><i>HYDROXYPROPYL METHYL CELLULOSE VISCOELASTIC SOLUTION</i>                                                              |      |
| HpmcGel 2.0%<br>Gonioscopy examination contact fluid 15 ml<br>(Gonyoskopi muayenesi temas sıvısı 15 ml)                                                                               | II A |
| <b>STERİL KAYGANLAŞTIRICI GÖZ DAMLASI</b><br><i>STERILE LUBRICANT EYE DROP</i>                                                                                                        |      |
| Ocufull Fresh                                                                                                                                                                         | II B |
| Ocufull Fresh Plus                                                                                                                                                                    | II B |

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| <b>ADRES BİLGİLERİ</b><br>ADDRESS INFORMATION                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | ÇALI MAH.14.(410) SOKAK NO:14B NİLÜFER / BURSA                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
| <b>TELEFON/ FAKS</b><br>TELEPHONE /FAX                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | 0224 441 33 34 / 0224 443 70 06                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
| <b>DEKLARASYON YAYIN TARİHİ/ YERİ</b><br>DECLARATION PUBLISHING<br>DATE/ PLACE                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | 19.03.2012 ATAKAN DEDE-MİRAY MEDİKAL                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
| <b>REVİZYON TARİHİ</b><br>REVISION DATE                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | 12.05.2021                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| <b>GEÇERLİLİK TARİHİ:</b><br>EXPIRY DATE                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | 26.05.2024                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| <b>UYGUNLUK DEĞERLENDİRMESİ</b><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).                                                                                                                                                                                                                                                                   |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
| <b>ONAYLANAN KURULUŞ</b><br>APPROVED COMPANY                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | ATAKAN DEDE-MİRAY MEDİKAL                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| <b>ONAYLAYAN KURULUŞ/ NOTIFIED BODY</b><br>ADRES/ ADDRESS                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | SZUTEST Uygunluk Değerlendirme A.Ş.<br>Tatlısu Mahallesi, Akif İnan Sk. No:1, 34774 Ümraniye/İstanbul/ TÜRKİYE                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
| <b>ONAYLAYAN KURULUŞUN KİMLİK NUMARASI :</b><br>NOTIFIED BODY ID NO                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | 2195                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
| <b>CE SERTİFİKA NUMARASI:</b><br>CE CERTIFICATE NO                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | 2195-MED-1207901                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
| <b>UYGULANAN STANDARTLAR/ APPLIED STANDARTS</b><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: 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><br>GMDN CODES                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | 37207: İrigasyon (yıkama) sıvısı (BSS) (Irrigation fluid (BSS))<br>35907: Aköz/vitröz hümmör 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)<br>44237: Lubrikant, Göz (Lubricant, Eye)                                                                                                                                                                                                                                                                                                                                                       |
| <b>UNSPC KODLARI</b><br>UNSPC CODES                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | 42293504/ Göz irigasyon (yıkama) veya aspirasyon malzemeleri veya aksesuarları (BSS) (Eye irrigation or aspiration materials or accessories (BSS))<br>42295126 / Göz cerrahisi için vitreoretinal fragmotom cerrahisi donanımı veya aksesuarları (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)<br>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

