


Deklaracja zgodności

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|-------------------|--|--|--|---------------|-------|---------------|-------|---------------|--------|---------------|--------|---------------|--------|---------------|--------|---------------|--------|---------------|--------|---------------|--------|---------------|--------|---------------|--------|---------------|--------|---------------|--------|---------------|---------|---------------|---------|---------------|---------|---------------|---------|---------------|---------|---------------|---------|---------------|-----------------|---------------|-----------------|
| Numer deklaracji: | DOC-02-0004 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Data deklaracji: | 03/09/2021 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Producent: |  TURKUAZ SAĞLIK HİZMETLERİ MEDİKAL TEMİZLİK KİMYASAL ÜRÜNLER SANAYİ VE TİCARET ANONİM ŞİRKETİ | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| SRN: | N/A | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Produkt: | Niesterylne żel do ultrasonografii | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| BUDI-DI: | 868171534101J8 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| UDI-DI: | <table border="1"> <tr><td>8698712450293</td><td>20 mL</td></tr> <tr><td>8698712457094</td><td>60 mL</td></tr> <tr><td>8698712450019</td><td>250 mL</td></tr> <tr><td>8681715349572</td><td>250 mL</td></tr> <tr><td>8681715349589</td><td>250 mL</td></tr> <tr><td>8681715349596</td><td>250 mL</td></tr> <tr><td>8681715349602</td><td>250 mL</td></tr> <tr><td>8681715349619</td><td>250 mL</td></tr> <tr><td>8681715349671</td><td>250 mL</td></tr> <tr><td>8681715349626</td><td>250 mL</td></tr> <tr><td>8681715349633</td><td>250 mL</td></tr> <tr><td>8698712450026</td><td>500 mL</td></tr> <tr><td>8681715349947</td><td>500 mL</td></tr> <tr><td>8698712450033</td><td>1000 mL</td></tr> <tr><td>8683229600514</td><td>1000 mL</td></tr> <tr><td>8681715349640</td><td>1000 mL</td></tr> <tr><td>8698712450057</td><td>5000 mL</td></tr> <tr><td>8681715349664</td><td>5000 mL</td></tr> <tr><td>8681715349688</td><td>5000 mL</td></tr> <tr><td>8698712450040</td><td>5000 mL (Galon)</td></tr> <tr><td>8681715349657</td><td>5000 mL (Galon)</td></tr> </table> | | | 8698712450293 | 20 mL | 8698712457094 | 60 mL | 8698712450019 | 250 mL | 8681715349572 | 250 mL | 8681715349589 | 250 mL | 8681715349596 | 250 mL | 8681715349602 | 250 mL | 8681715349619 | 250 mL | 8681715349671 | 250 mL | 8681715349626 | 250 mL | 8681715349633 | 250 mL | 8698712450026 | 500 mL | 8681715349947 | 500 mL | 8698712450033 | 1000 mL | 8683229600514 | 1000 mL | 8681715349640 | 1000 mL | 8698712450057 | 5000 mL | 8681715349664 | 5000 mL | 8681715349688 | 5000 mL | 8698712450040 | 5000 mL (Galon) | 8681715349657 | 5000 mL (Galon) |
| 8698712450293 | 20 mL | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 8698712457094 | 60 mL | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 8698712450019 | 250 mL | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 8681715349572 | 250 mL | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 8681715349589 | 250 mL | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 8681715349596 | 250 mL | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 8681715349602 | 250 mL | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 8681715349619 | 250 mL | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 8681715349671 | 250 mL | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 8681715349626 | 250 mL | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 8681715349633 | 250 mL | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 8698712450026 | 500 mL | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 8681715349947 | 500 mL | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 8698712450033 | 1000 mL | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 8683229600514 | 1000 mL | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 8681715349640 | 1000 mL | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 8698712450057 | 5000 mL | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 8681715349664 | 5000 mL | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 8681715349688 | 5000 mL | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 8698712450040 | 5000 mL (Galon) | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 8681715349657 | 5000 mL (Galon) | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| UDI-PI: | [(10) LOT / BATCH NO] [(11) ÜRT / PRD DATE] [(17) SKT / EXP DATE] | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Numer katalogowy: | <table border="1"> <tr><td>NUG-0001</td><td>20 MI</td></tr> <tr><td>SUG-0002</td><td>60 mL</td></tr> <tr><td>NUG-0003</td><td>250 mL</td></tr> </table> | | | NUG-0001 | 20 MI | SUG-0002 | 60 mL | NUG-0003 | 250 mL | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| NUG-0001 | 20 MI | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| SUG-0002 | 60 mL | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| NUG-0003 | 250 mL | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |


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|------------------|-----------------|---------------|----------|----------------|---|---------------|----------|---------|-------|
| Numer dokumentu: | TF011.01.00.002 | Data wydania: | 3.9.2021 | Numer rewizji: | 0 | Data rewizji: | 3.9.2021 | Strona: | 1 / 5 |
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|---------------|--|----------------|-----------------|
| | | NUG-0004 | 250 mL |
| | | NUG-0005 | 250 mL |
| | | NUG-0006 | 250 mL |
| | | NUG-0007 | 250 mL |
| | | NUG-0008 | 250 mL |
| | | NUG-0009 | 250 mL |
| | | NUG-0010 | 250 mL |
| | | NUG-0011 | 250 mL |
| | | NUG-0019 | 500 mL |
| | | NUG-0020 | 500 mL |
| | | NUG-0012 | 1000 mL |
| | | NUG-0012 | 1000 mL |
| | | NUG-0013 | 1000 mL |
| | | NUG-0016 | 5000 mL |
| | | NUG-0017 | 5000 mL |
| | | NUG-0018 | 5000 mL |
| | | NUG-0014 | 5000 mL (Galon) |
| | | NUG-0015 | 5000 mL (Galon) |
| Numer modelu: | | Y0000.101.0013 | 20 mL |
| | | Y0000.101.0039 | 60 mL |
| | | Y0000.101.0001 | 250 mL |
| | | Y0000.101.0002 | 250 mL |
| | | Y0000.101.0003 | 250 mL |
| | | Y0000.101.0004 | 250 mL |
| | | Y0000.101.0032 | 250 mL |
| | | Y0000.101.0059 | 250 mL |
| | | Y0000.101.0066 | 250 mL |
| | | Y0000.101.0077 | 250 mL |
| | | Y0000.101.0062 | 250 mL |
| | | Y0000.101.0005 | 500 mL |
| | | Y0000.101.0006 | 500 mL |
| | | Y0000.101.0016 | 1000 mL |
| | | Y0000.101.0018 | 1000 mL |
| | | Y0000.101.0017 | 1000 mL |
| | | Y0000.101.0011 | 5000 mL |
| | | Y0000.101.0012 | 5000 mL |


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| Numer dokumentu: | TF011.01.00.002 | Data wydania: | 3.9.2021 | Numer rewizji: | 0 | Data rewizji: | 3.9.2021 | Strona: | 2 / 5 |
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|-------------------|---|----------------|--------------------|--|
| | | Y0000.101.0063 | 5000 mL | |
| | | Y0000.101.0009 | 5000 mL (Galon) | |
| | | Y0000.101.0010 | 5000 mL (Galon) | |
| Marka: | KONIX | | | |
| Przeznaczenie: | Niesterylny żel do ultrasonografii używany jest do obrazowania uktradźwiękowego i odpowiedniego nawilżenia powierzchni badanej. | | | |
| Zdjęcie produktu: |  | | | |

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| Numer dokumentu: | TF011.01.00.002 | Data wydania: | 3.9.2021 | Numer rewizji: | 0 | Data rewizji: | 3.9.2021 | Strona: | 3 / 5 |
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| Wspólna specyfikacja: | EN ISO 13485, EN ISO 14971, EN ISO 62366, EN ISO 14644-1, EN ISO 10993-1, EN ISO 10993-5, EN ISO 10993-10, EN ISO 15223-1, EN ISO 14698-1, ISO 16142-1, ISO/TR 20416, ISO 20417 |
| GMDN: | <p>15321</p> <p><i>Żel, przewodnictwo fal ultradźwiękowych</i></p> <p><i>Substancja zapewniająca lepszy kontakt, odbiór i transmisję fal ultradźwiękowych przechodzących przez skórę podczas badania ultrasonograficznego. Pomaga również operatorowi płynnie przesuwac sondę po skórze.</i></p> |
| Dyrektywy i legislacje UE: | - 02.06.2021 Tarih 31499 Sayılı Mükerrer Resmi Gazete / Tıbbi Cihaz Yönetmeliği <i>Regulacja (UE) 2017/745</i> |
| Klasyfikacja ryzyka: | Sınıf I, Ek VIII, Kural I <i>Klasa I, Aneks VIII, Regula I</i> |
| Linia zgodności: | MDR Ek IV (Ek II ve Ek III) <i>MDR Aneks IV (Aneks II i Aneks III)</i> |
| Deklaracja: | İşbu AB Uygunluk Beyanı, TURKUAZ SAĞLIK HİZMETLERİ MEDİKAL TEMİZLİK KİMYASAL ÜRÜNLER SANAYİ VE TİCARET ANONİM ŞİRKETİ sorumluluğunda yayınlanmıştır. Beyanda bahse konu tıbbi cihazın, ilgili AB direktifi ve varsa, bir AB Uygunluk beyanı |

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| Numer dokumentu: | TF011.01.00.002 | Data wydania: | 3.9.2021 | Numer rewizji: | 0 | Data rewizji: | 3.9.2021 | Strona: | 4 / 5 |
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| | <p>düzenlenmesini sağlayan diğer ilgili AB mevzuatıyla uyumlu olduğu beyan edilmektedir.</p> <p><i>Niniejsza Deklaracja Zgodności UE została wydana na wyłączną odpowiedzialność TURKUAZ SAĞLIK HİZMETLERİ MEDİKAL TEMİZLİK KİMYASAL ÜRÜNLER SANAYİ VE TİCARET ANONİM ŞİRKETİ. W deklaracji stwierdza się, że dany wyrób medyczny jest zgodny z odpowiednią dyrektywą UE oraz, jeśli takie istnieją, z innymi odpowiednimi przepisami UE umożliwiającymi wysatwienie Deklaracji Zgodności UE.</i></p> | |
| Osoba deklarująca: | <p>KYT / QMR</p> <p>Hanifi Karahan Bozkurt Arge ve Kalite Direktörü R&D and Quality Director</p> |  |
| Miejsce deklaracji: | Akçaburgaz Mah. Muhsin Yazıcıoğlu Cad. No:45/5 34522 Esenyurt / Stambul, Turcja | |
| Jednostka notyfikowana: | N/A | |
| Certyfikat UE: | N/A | |
| Certyfikat projektu: | N/A | |
| Numer dokumentu technicznego: | TF011.01 | |
| Autoryzowany reprezentant UE: | N/A | |
| Informacje dodatkowe: | <p>Bu uygunluk deklarasyonu ürünlerin pazara arz edildiği tüm ülkelerde, o ülkenin dilinde hazırlanmış kullanım kılavuz ve etiketleriyle ve yetkili ithalatçı veya distribütörünün sorumluluğuyla geçerlidir.</p> <p><i>Niniejsza Deklaracja Zgodności jest ważna z etykietami i IFU, sporządzonymi w lokalnym języku, w którym produkty zostały wprowadzone do obrotu na odpowiedzialność autoryzowanego importera lub dystrybutora.</i></p> | |

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| Numer dokumentu: | TF011.01.00.002 | Data wydania: | 3.9.2021 | Numer rewizji: | 0 | Data rewizji: | 3.9.2021 | Strona: | 5 / 5 |
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