

**AB UYGUNLUK BEYANI**  
**AB DECLARATION OF CONFORMITY**

|                                                      |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |               |       |               |       |               |        |               |        |               |        |               |        |               |        |               |        |               |        |               |        |               |        |               |        |               |        |               |         |               |         |               |         |               |         |               |         |               |         |               |                    |               |                    |               |                                |               |                              |
|------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------|-------|---------------|-------|---------------|--------|---------------|--------|---------------|--------|---------------|--------|---------------|--------|---------------|--------|---------------|--------|---------------|--------|---------------|--------|---------------|--------|---------------|--------|---------------|---------|---------------|---------|---------------|---------|---------------|---------|---------------|---------|---------------|---------|---------------|--------------------|---------------|--------------------|---------------|--------------------------------|---------------|------------------------------|
| <b>Beyanname No</b><br><b>Declaration Nu:</b>        | DOC-02-0004                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |               |       |               |       |               |        |               |        |               |        |               |        |               |        |               |        |               |        |               |        |               |        |               |        |               |        |               |         |               |         |               |         |               |         |               |         |               |         |               |                    |               |                    |               |                                |               |                              |
| <b>Beyanname Tarihi:</b><br><b>Declaration Date:</b> | 03/09/2021                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |               |       |               |       |               |        |               |        |               |        |               |        |               |        |               |        |               |        |               |        |               |        |               |        |               |        |               |         |               |         |               |         |               |         |               |         |               |         |               |                    |               |                    |               |                                |               |                              |
| <b>Üretici:</b><br><b>Manufacturer:</b>              | <br>TURKUAZ SAĞLIK HİZMETLERİ MEDİKAL TEMİZLİK<br>KİMYASAL ÜRÜNLER SANAYİ VE TİCARET ANONİM ŞİRKETİ                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |               |       |               |       |               |        |               |        |               |        |               |        |               |        |               |        |               |        |               |        |               |        |               |        |               |        |               |         |               |         |               |         |               |         |               |         |               |         |               |                    |               |                    |               |                                |               |                              |
| <b>Münferit Kimlik No / SRN:</b>                     | TR-MF-000015402                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |               |       |               |       |               |        |               |        |               |        |               |        |               |        |               |        |               |        |               |        |               |        |               |        |               |        |               |         |               |         |               |         |               |         |               |         |               |         |               |                    |               |                    |               |                                |               |                              |
| <b>Ürün(ler):</b><br><b>Product(s):</b>              | NON-STERİL ULTRASON JEL<br>NON-STERILE ULTRASOUND GEL                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |               |       |               |       |               |        |               |        |               |        |               |        |               |        |               |        |               |        |               |        |               |        |               |        |               |        |               |         |               |         |               |         |               |         |               |         |               |         |               |                    |               |                    |               |                                |               |                              |
| <b>Temel UDI-DI / BUDI-DI:</b>                       | 868171534101J8                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |               |       |               |       |               |        |               |        |               |        |               |        |               |        |               |        |               |        |               |        |               |        |               |        |               |        |               |         |               |         |               |         |               |         |               |         |               |         |               |                    |               |                    |               |                                |               |                              |
| <b>UDI-DI:</b>                                       | <table><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<br/>(Galon)</td></tr><tr><td>8681715349657</td><td>5000 mL<br/>(Galon)</td></tr><tr><td>8683229601344</td><td>5000 mL<br/>(Şeffaf Cubitainer)</td></tr><tr><td>8683229601351</td><td>5000 mL<br/>(Mavi Cubitainer)</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<br>(Galon) | 8681715349657 | 5000 mL<br>(Galon) | 8683229601344 | 5000 mL<br>(Şeffaf Cubitainer) | 8683229601351 | 5000 mL<br>(Mavi Cubitainer) |
| 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<br>(Galon)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |               |       |               |       |               |        |               |        |               |        |               |        |               |        |               |        |               |        |               |        |               |        |               |        |               |        |               |         |               |         |               |         |               |         |               |         |               |         |               |                    |               |                    |               |                                |               |                              |
| 8681715349657                                        | 5000 mL<br>(Galon)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |               |       |               |       |               |        |               |        |               |        |               |        |               |        |               |        |               |        |               |        |               |        |               |        |               |        |               |         |               |         |               |         |               |         |               |         |               |         |               |                    |               |                    |               |                                |               |                              |
| 8683229601344                                        | 5000 mL<br>(Şeffaf Cubitainer)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |               |       |               |       |               |        |               |        |               |        |               |        |               |        |               |        |               |        |               |        |               |        |               |        |               |        |               |         |               |         |               |         |               |         |               |         |               |         |               |                    |               |                    |               |                                |               |                              |
| 8683229601351                                        | 5000 mL<br>(Mavi Cubitainer)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |               |       |               |       |               |        |               |        |               |        |               |        |               |        |               |        |               |        |               |        |               |        |               |        |               |        |               |         |               |         |               |         |               |         |               |         |               |         |               |                    |               |                    |               |                                |               |                              |
| <b>UDI-PI:</b>                                       | [(10) LOT / BATCH NO]<br>[(11) ÜRT / PRD DATE]<br>[(17) SKT / EXP DATE]                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |               |       |               |       |               |        |               |        |               |        |               |        |               |        |               |        |               |        |               |        |               |        |               |        |               |        |               |         |               |         |               |         |               |         |               |         |               |         |               |                    |               |                    |               |                                |               |                              |

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| Doküman No /<br>Document Nu: | TF011.01.00.002 | Yayın Tarihi /<br>Release Date: | 17.12.2021 | Revizyon No /<br>Revision Nu: | 1 | Revizyon Tarihi /<br>Revision Date: | 17.12.2021 | Sayfa No /<br>Page Nu: | 1 / 5 |
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TURKUAZ SAĞLIK HİZMETLERİ MEDİKAL TEMİZLİK KİMYASAL ÜRÜNLER SANAYİ VE TİCARET ANONİM ŞİRKETİ

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**AB UYGUNLUK BEYANI**  
**AB DECLARATION OF CONFORMITY**

**Referans/Katalog No:**  
**Reference/Catalogue Number:**

|          |                                |
|----------|--------------------------------|
| NUG-0001 | 20 Ml                          |
| SUG-0002 | 60 mL                          |
| NUG-0003 | 250 mL                         |
| 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<br>(Galon)             |
| NUG-0015 | 5000 mL<br>(Galon)             |
| NUG-0016 | 5000 mL<br>(Şeffaf Cubitainer) |
| NUG-0017 | 5000 mL<br>(Mavi Cubitainer)   |

**Versiyon/Model No:**  
**Version/Model Number:**

|                |        |
|----------------|--------|
| 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 |

|                              |                 |                                 |            |                               |   |                                     |            |                        |       |
|------------------------------|-----------------|---------------------------------|------------|-------------------------------|---|-------------------------------------|------------|------------------------|-------|
| Doküman No /<br>Document Nu: | TF011.01.00.002 | Yayın Tarihi /<br>Release Date: | 17.12.2021 | Revizyon No /<br>Revision Nu: | 1 | Revizyon Tarihi /<br>Revision Date: | 17.12.2021 | Sayfa No /<br>Page Nu: | 2 / 5 |
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**TURKUAZ SAĞLIK HİZMETLERİ MEDİKAL TEMİZLİK KİMYASAL ÜRÜNLER SANAYİ VE TİCARET ANONİM ŞİRKETİ**

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**AB DECLARATION OF CONFORMITY**

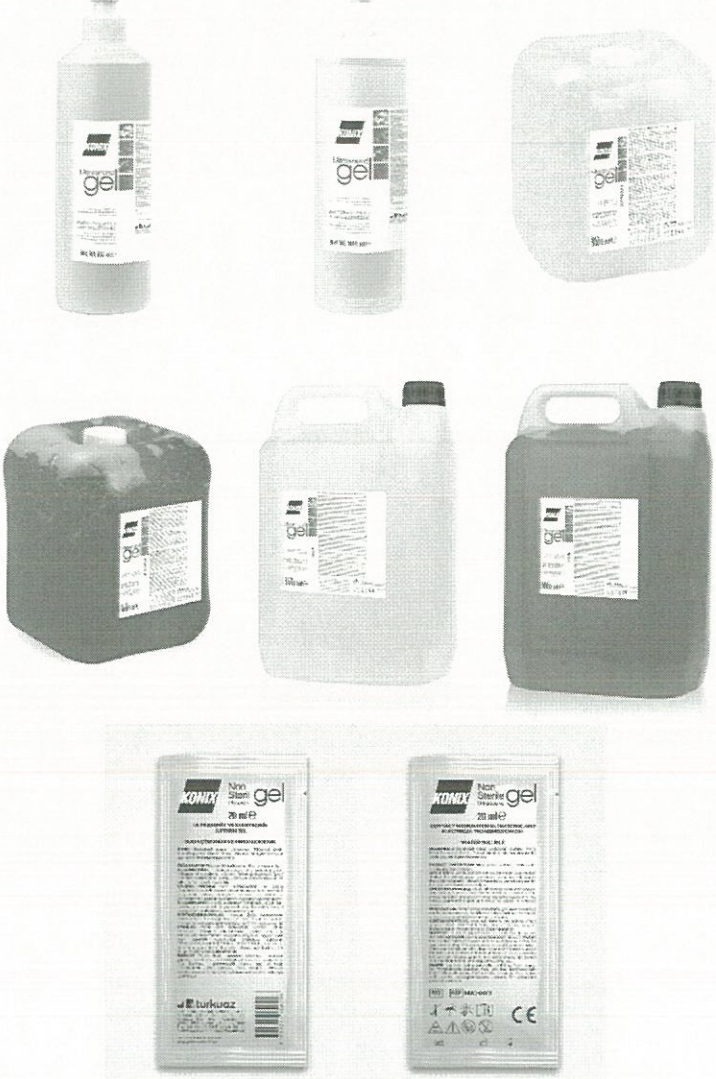
|                                                |                                                                                                                                                                              |                |                                |
|------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------------------------|
|                                                |                                                                                                                                                                              | 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                        |
|                                                |                                                                                                                                                                              | Y0000.101.0063 | 5000 mL                        |
|                                                |                                                                                                                                                                              | Y0000.101.0009 | 5000 mL<br>(Galon)             |
|                                                |                                                                                                                                                                              | Y0000.101.0010 | 5000 mL<br>(Galon)             |
|                                                |                                                                                                                                                                              | Y0000.101.0083 | 5000 mL<br>(Şeffaf Cubitainer) |
|                                                |                                                                                                                                                                              | Y0000.101.0084 | 5000 mL<br>(Mavi Cubitainer)   |
| <b>Marka:</b><br><b>Trademark:</b>             | KONIX                                                                                                                                                                        |                |                                |
| <b>Kullanım Amacı:</b><br><b>Intended Use:</b> | Non-Steril Ultrason Jel ultrason uygulamalarında görüntü ve kaydırma amaçlı kullanılır.<br><i>Non-Sterile Ultrasound Gel is used for ultrasonic imaging and lubrication.</i> |                |                                |
| <b>Ürün Görseli:</b><br><b>Product Photo:</b>  |                                                                                          |                |                                |

|                              |                 |                                 |            |                               |   |                                     |            |                        |       |
|------------------------------|-----------------|---------------------------------|------------|-------------------------------|---|-------------------------------------|------------|------------------------|-------|
| Doküman No /<br>Document Nu: | TF011.01.00.002 | Yayın Tarihi /<br>Release Date: | 17.12.2021 | Revizyon No /<br>Revision Nu: | 1 | Revizyon Tarihi /<br>Revision Date: | 17.12.2021 | Sayfa No /<br>Page Nu: | 3 / 5 |
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**TURKUAZ SAĞLIK HİZMETLERİ MEDİKAL TEMİZLİK KİMYASAL ÜRÜNLER SANAYİ VE TİCARET ANONİM ŞİRKETİ**

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**AB UYGUNLUK BEYANI**  
**AB DECLARATION OF CONFORMITY**

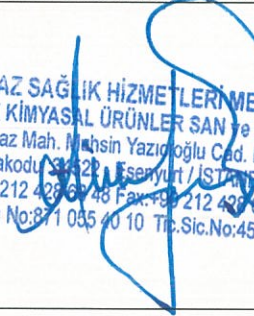
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|-----------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                                                           |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
| <b>Ortak Özellikler:</b><br><i>Common Specifications:</i> | 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                                                                                                                                                                                                                                                                                                                                                                                                               |
| <b>GMDN:</b>                                              | 15321<br>Jel, ultrasonik bağlama<br>Bir ultrason incelemesi sırasında deri içinden geçen ultrasonik dalgaların alınması ve verilmesi için iyileştirilmiş temas ve şartların sağlandığı bir madde. Ayrıca operatörün probu cilt üzerinde düzgün bir şekilde hareket ettirebilmesine de yardımcı olmaktadır.<br>15321<br>Gel, ultrasonic bonding<br>A substance that provides improved contact and conditions for receiving and transmitting ultrasonic waves that pass through the skin during an ultrasound examination. It also helps the operator to move the probe smoothly over the skin. |

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| <b>AB Direktifi ve Mevzuat</b><br><b>EU Directive and Legislation:</b>                       | - 02.06.2021 Tarih 31499 Sayılı Mükerrer Resmi Gazete / Tıbbi Cihaz Yönetmeliği<br><i>Regulation (EU) 2017/745</i>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |                                                                                                                                                                                                                                                                                                                                                                   |
| <b>Risk Sınıfı:</b><br><b>Risk Classification:</b>                                           | Sınıf I, Ek VIII, Kural I<br><i>Class I, Annex VIII, Rule I</i>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |                                                                                                                                                                                                                                                                                                                                                                   |
| <b>Uygunluk Yolu: Conformity Route:</b>                                                      | MDR Ek IV (Ek II ve Ek III)<br><i>MDR Annex IV (Annex II and Annex III)</i>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |                                                                                                                                                                                                                                                                                                                                                                   |
| <b>Beyan:</b><br><b>Declaration:</b>                                                         | <p>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 düzenlenmesini sağlayan diğer ilgili AB mevzuatıyla uyumlu olduğu beyan edilmektedir.</p> <p><i>This EU Declaration of Conformity is issued under the sole responsibility of the TURKUAZ SAĞLIK HİZMETLERİ MEDİKAL TEMİZLİK KİMYASAL ÜRÜNLER SANAYİ VE TİCARET ANONİM ŞİRKETİ. In the declaration, it is declared that the medical device in question is in compliance with the relevant EU directive and, if any, other relevant EU legislation enabling the issuance of an EU Declaration of Conformity.</i></p> |                                                                                                                                                                                                                                                                                                                                                                   |
| <b>Beyan Eden:</b><br><b>Declarant:</b>                                                      | KYT / QMR<br><br>Hanifi Karahan<br>Bozkurt<br>Arge ve Kalite<br>Direktörü<br><i>R&amp;D and Quality Director</i>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | <br>TURKUAZ SAĞLIK HİZMETLERİ MEDİKAL<br>TEMİZLİK KİMYASAL ÜRÜNLER SAN. VE TİC. A.Ş.<br>Akçaburgaz Mah. Muhsin Yazıcıoğlu Cad. No:45/5<br>Postakodu: 34522 Esenyurt / İSTANBUL<br>Tel: +90 212 428 6848 Fax: +90 212 428 6853<br>Yenikapı No: 871 035 40 10 Tic.Sic.No: 450836 |
| <b>Onaylı Kuruluş:</b><br><b>Notified Body:</b>                                              | N/A                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |                                                                                                                                                                                                                                                                                                                                                                   |
| <b>AB Sertifikası:</b><br><b>EU Certificate:</b>                                             | N/A                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |                                                                                                                                                                                                                                                                                                                                                                   |
| <b>Tasarım Sertifikası:</b><br><b>Design Certificate:</b>                                    | N/A                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |                                                                                                                                                                                                                                                                                                                                                                   |
| <b>Teknik Dosya No ve Saklama Adresi:</b><br><b>Technical File Nu and Retention Address:</b> | TF011.01                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |                                                                                                                                                                                                                                                                                                                                                                   |
| <b>AB Yetkili Temsilci:</b><br><b>EU Authorized Representative:</b>                          | N/A                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |                                                                                                                                                                                                                                                                                                                                                                   |
| <b>Ek Bilgi:</b><br><b>Additional Information:</b>                                           | <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>This declaration of conformity is valid with labels and IFUs prepared in the local language where the products have been marketed under the responsibility of the authorised importer or distributor.</i></p>                                                                                                                                                                                                                                                                                                                             |                                                                                                                                                                                                                                                                                                                                                                   |

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