

## EC CERTIFICATE AT SERTİFİKA

According to Annex II of the Directive 93/42/EEC on Medical Devices  
93/42/AT Tıbbi Cihaz Yönetmeliği Ek II'ye göre

### Full Quality Assurance System Tam Kalite Güvencesi

Certificate Number: 2195-MED-1110901  
Sertifika Numarası

Manufacturer:  
Üretici

Farmasol Tıbbi Ürünler San. ve Tic. A.Ş.  
Organize Sanayi Bölgesi 18. Cad. No:7 Melikgazi Kayseri Türkiye

Product(s):  
Ürün(ler)

1. Acidic Bicarbonate Haemodialysis Solutions  
Asidik Bikarbonat Hemodiyaliz Solüsyonları
2. Basic Bicarbonate Haemodialysis Solutions  
Bazik Bikarbonat Hemodiyaliz Solüsyonları
3. Powder Acidic Haemodialysis Concentrate  
Toz Asidik Hemodiyaliz Konsantresi
4. Powder Sodium Bicarbonate  
Toz Sodyum Bikarbonat
5. Haemodialysis Machine Disinfectant  
Hemodiyaliz Makinası Dezenfektanı
6. Sterile Arteriovenous Set and Fistula Needle  
Steril Arter Ven Seti ve Fistül İğnesi

Model(s):  
Model(ler)

Product models are stated on the next pages.  
Ürün modelleri diğer sayfalarda belirtilmiştir.

Reference Report No:  
Referans Rapor No

MM0192-P001-R01, MM0192-P001-R02, MM0192-P003-R01, MM0192-P003-R02,  
MM0192-P003-R03, MM0192-P004-R01, MM0192-P004-R02, MM0192-P004-R03,  
MM0192-P007-R02, MM0192-P007-R03, MM0192-P007-R04, MM0192-P007-R05

Szutest, Notified Body 2195, declares that the aforementioned manufacturer has implemented a quality assurance system according to Annex II (excluding section 4), Section 3 of the directive 93/42/EEC on medical devices. This quality assurance system covers those aspects of manufacturing concerned with securing and maintaining safe conditions of the respective product(s) and conforms to the provisions of this Directive. The approved quality system is subject to surveillance pursuant to Annex II, Section 5 of Directive 93/42/EEC and unannounced audits.

Szutest must be informed of any significant changes in the design and/or construction of the product(s).

2195 kimlik numaralı Onaylanmış Kuruluş Szutest, yukarıda belirtilen üreticinin 93/42/AT Tıbbi Cihaz Yönetmeliği EK II (madde 4 hariç) madde 3'üne göre bir kalite yönetim sistemi uyguladığını, bu yönetim sisteminin yönetmeliğin sadece bahsi geçen ürünün üretiminin güvenlik koşullarını sağlama ve devam ettirme ile ilgili gerekliliklerin karşıladığını beyan eder. Onaylanan bu kalite yönetim sistemi, 93/42/AT Tıbbi Cihaz Yönetmeliği EK II, Madde 5'e göre periyodik olarak gözetime ve habersiz saha denetimlerine tabidir. Üretici, ürünlerinin tasarımında ve yapısında gerçekleştirdiği önemli değişiklikleri Szutest'e bildirmek zorundadır.

This EC certificate is valid till 2019-04-18.  
Bu AT Sertifikası 2019-04-18 tarihine kadar geçerlidir.

Issue Date/Yayın Tarihi: 2011-04-19  
Revision No./ Revizyon No.: 07 Rev./Rev.  
Revision Date/ Revizyon Tarihi: 2018-10-22





Rukye BALKAN  
Deputy General Manager  
Genel Müdür Yardımcısı



# SZUTEST

Certificate Number: 2195-MED-1110901

Sertifika Numarası

## Product Models

Ürün Modelleri

### 1. Acidic Bicarbonate Haemodialysis Solutions

Asidik Bikarbonat Hemodiyaliz Solüsyonları

- |                               |                                   |                              |
|-------------------------------|-----------------------------------|------------------------------|
| 1. MEDICASOL K1Ca1,5Ac2       | 33. MEDICASOL K2Ca1,5Mg1          | 65. MEDICASOL K1GCa1,25Ac5   |
| 2. MEDICASOL K1GCa1,5         | 34. MEDICASOL K1GCa1,5 (D45)      | 66. MEDICASOL K3G Ca 1.25    |
| 3. MEDICASOL K1GCa1,5Ac2      | 35. MEDICASOL K2GCa1,5Mg1         | 67. MEDICASOL K1Ca1,75Ac5    |
| MEDICASOL K1Ca1,75            | 36. MEDICASOL K1Ca1,75 (D45)      | 68. MEDICASOL K3 Ca 1.5      |
| 5. MEDICASOL K2Ca1,5Ac2       | 37. MEDICASOL K2Ca1,75Mg1         | 69. MEDICASOL K1GCa1,75Ac5   |
| 6. MEDICASOL K1GCa1,75        | 38. MEDICASOL K1GCa1,75 (D45)     | 70. MEDICASOL K3G Ca 1.5     |
| 7. MEDICASOL K2GCa1,5Ac2      | 39. MEDICASOL K2GCa1,75Mg1        | 71. MEDICASOL K1,5Ca1,5Ac2   |
| 8. MEDICASOL K1,5Ca1,25       | 40. MEDICASOL K1,5Ca1,25 (D45)    | 72. MEDICASOL Ca1,5 K2       |
| 9. MEDICASOL K2Ca1,25Ac2      | 41. MEDICASOL Ca1,25K2G           | 73. MEDICASOL K1,5GCa1,5Ac2  |
| 10. MEDICASOL K1,5GCa1,25     | 42. MEDICASOL K1,5GCa1,25 (D45)   | 74. MEDICASOL K3 Ca 1.75     |
| 11. MEDICASOL K2GCa1,25Ac2    | 43. MEDICASOL Ca1,25K3G           | 75. MEDICASOL K1Ca1,75Ac2    |
| 12. MEDICASOL K1,5Ca1,5       | 44. MEDICASOL K1.5 Ca 1.5 (D45)   | 76. MEDICASOL K3G Ca 1.75    |
| 13. MEDICASOL K1Ca1,25Ac2     | 45. MEDICASOL Ca1,5K2G            | 77. MEDICASOL K1GCa1,75Ac2   |
| 14. MEDICASOL K1,5GCa1,5      | 46. MEDICASOL K1.5G Ca 1.5 (D45)  | 78. MEDICASOL K1G2Ca1,5Ac2   |
| 15. MEDICASOL K1GCa1,25Ac2    | 47. MEDICASOL Ca1,5K3G            | 79. MEDICASOL K2Ca1Ac2       |
| 16. MEDICASOL K1,5Ca1,75      | 48. MEDICASOL K1.5 Ca1.75 (D45)   | 80. MEDICASOL K2G2Ca1,5Ac2   |
| 17. MEDICASOL K2Ca1,5         | 49. MEDICASOL Ac8                 | 81. MEDICASOL K2GCa1Ac2      |
| 18. MEDICASOL K1,5GCa1,75     | 50. MEDICASOL K1.5G Ca 1,75 (D45) | 82. MEDICASOL K2G2Ca1,25Ac2  |
| 19. MEDICASOL Ca1,5K3         | 51. MEDICASOL K2Ca1,25Ac5         | 83. MEDICASOL K2Ca1,75Ac2    |
| 20. MEDICASOL K2Ca1,25        | 52. MEDICASOL K2 Ca 1,25 (D45)    | 84. MEDICASOL K3G2Ca1,5Ac2   |
| 21. MEDICASOL K2Ca1,75        | 53. MEDICASOL K2GCa1,25Ac5        | 85. MEDICASOL K2GCa1,75Ac2   |
| 22. MEDICASOL K2GCa1,25       | 54. MEDICASOL K2G Ca 1.25 (D45)   | 86. MEDICASOL K3Ca1,5Ac2     |
| 23. MEDICASOL K2Ca1,75Ac5     | 55. MEDICASOL K1Ca1,5Ac4          | 87. MEDICASOL K3GCa1,5Ac2    |
| 24. MEDICASOL K2G Ca 1,5      | 56. MEDICASOL K2G Ca 1.5 (D45)    | 88. MEDICASOL K1,5Ca1,25Ac2  |
| 25. MEDICASOL K2Ca1,25Ac4     | 57. MEDICASOL K2GCa1,75Ac5        | 89. MEDICASOL K1,5GCa1,25Ac2 |
| 26. MEDICASOL K2GCa1,75       | 58. MEDICASOL K2 Ca 1.75(D45)     | 90. MEDICASOL K1,5Ca1,75Ac2  |
| 27. MEDICASOL K1Ca1,5GAc4     | 59. MEDICASOL K2Ca1,5Ac5          | 91. MEDICASOL K1,5GCa1,75Ac2 |
| 28. MEDICASOL K1Ca1,25 (D45)  | 60. MEDICASOL K2G Ca 1.75 (D45)   | 92. MEDICASOL K3Ca1,25Ac2    |
| 29. MEDICASOL K2Ca1,25Mg1     | 61. MEDICASOL K2GCa1,5Ac5         | 93. MEDICASOL K3GCa1,25Ac2   |
| 30. MEDICASOL K1GCa1,25 (D45) | 62. MEDICASOL K1Ca1,25            | 94. MEDICASOL K1GCa1,25      |
| 31. MEDICASOL K2GCa1,25Mg1    | 63. MEDICASOL K1Ca1,25Ac5         | 95. MEDICASOL K1Ca1,5        |
| 32. MEDICASOL K1Ca1,5 (D45)   | 64. MEDICASOL K3Ca1,25            |                              |

### 2. Basic Bicarbonate Haemodialysis Solutions

Bazik Bikarbonat Hemodiyaliz Solüsyonları

- |                  |                  |               |
|------------------|------------------|---------------|
| 1. DIASOL B35    | 2. DIASOL B37    | 3. DIASOL B39 |
| 4. MEDICASOL B35 | 5. MEDICASOL B39 |               |



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# SZUTEST

Certificate Number: 2195-MED-1110901

Sertifika Numarası

## Product Models

Ürün Modelleri

### 1. Acidic Bicarbonate Haemodialysis Solutions

Asidik Bikarbonat Hemodiyaliz Solüsyonları

- |                            |                             |                                       |
|----------------------------|-----------------------------|---------------------------------------|
| 1. DIASOL K 1              | 51. DIASOL Na138 K3         | 101. DIASOL Na140 K1 Ac5              |
| 2. DIASOL K 1 G            | 52. DIASOL Na138 K3G        | 102. DIASOL Na140 K1G Ac5             |
| 3. DIASOL K 2              | 53. DIASOL Na140 Ac3        | 103. DIASOL Na140 K1 Ca1,75           |
| 4. DIASOL K 2 G            | 54. DIASOL Na138 Ac3        | 104. DIASOL Na140 K1G Ca1,75          |
| 5. DIASOL Ca 1,25          | 55. DIASOL K1 Ac3           | 105. DIASOL Na140 K1,5                |
| 6. DIASOL Ca 1,25G         | 56. DIASOL Ca 1,75 Ac3      | 106. DIASOL Na140 K1,5G               |
| 7. DIASOL Ca1,25 K2        | 57. DIASOL Ca1,75 Ac5       | 107. DIASOL Na140 K2G Ac3             |
| 8. DIASOL Ca1,25 K2G       | 58. DIASOL Na140 Ac4        | 108. DIASOL Ca1,75 K1 Ac2             |
| 9. DIASOL Ca 1,75          | 59. DIASOL Na140 K1 Ac4     | 109. DIASOL Ca1,75 K1G Ac2            |
| 10. DIASOL K 1,5           | 60. DIASOL K1G Ac3          | 110. DIASOL Ca1 K2 Ac2                |
| 11. DIASOL K 1,5 G         | 61. DIASOL Ca1K2G           | 111. DIASOL Ca1K2GAc2                 |
| 12. DIASOL K3              | 62. DIASOL Ca1 K3           | 112. DIASOL Ca1,75 K2 Ac2             |
| 13. DIASOL K3G             | 63. DIASOL Ca1K3G           | 113. DIASOL Ca1,75 K2G Ac2            |
| 14. DIASOL İDEAL           | 64. DIASOL Ca1,75 K1        | 114. DIASOL Ca1,5 K3 Ac2              |
| 15. DIASOL GAMBRO K 2      | 65. DIASOL Ca1,75K1G        | 115. DIASOL Ca1,5 K3G Ac2             |
| 16. DIASOL GAMBRO K 2 G    | 66. DIASOL Ca1,25Mg1        | 116. DIASOL Ca1,25 K1,5 Ac2           |
| 17. DIASOL K1 Ac4          | 67. DIASOL Ca1,25GMg1       | 117. DIASOL Ca1,25 K1,5G Ac2          |
| 18. DIASOL K1G Ac4         | 68. DIASOL Ca1,5Mg1         | 118. DIASOL Ca1,75 K1,5 Ac2           |
| 19. DIASOL Na140 K2        | 69. DIASOL Ca1,5GMg1        | 119. DIASOL Ca1,75 K1,5G Ac2          |
| 20. DIASOL Na140 K2G       | 70. DIASOL Ca1,75Mg1        | 120. DIASOL Ca1,25 K3 Ac2             |
| 21. DIASOL Na140 Ca1,25    | 71. DIASOL Ca1,75GMg1       | 121. DIASOL Ca1,25 K3G Ac2            |
| 22. DIASOL Na140 Ca1,25G   | 72. DIASOL Ca1,25K1Mg1      | 122. DIASOL K1G Ca1,25 Ac3            |
| 23. DIASOL Ca1,25 K1       | 73. DIASOL Ca1,25K1GMg1     | 123. DIASOL K1 Ca1,5 Ac3              |
| 24. DIASOL Ca1,25 K1G      | 74. DIASOL Ca1,5K1Mg1       | 124. DIASOL K1G Ca1,5 Ac3             |
| 25. DIASOL K2 Ac2          | 75. DIASOL Ca1,5K1GMg1      | 125. DIASOL K1 Ca1,75 Ac3             |
| 26. DIASOL K2G Ac2         | 76. DIASOL Na138 K2G Ca1.25 | 126. DIASOL K1G Ca1,75 Ac3            |
| 27. DIASOL Ca1,25 K2 Ac2   | 77. DIASOL Na138 K3G Ca1,25 | 127. DIASOL K1,5 Ca1,25 Ac3           |
| 28. DIASOL Ca1,25 K2G Ac2  | 78. DIASOL Na138 K2G Ca1.50 | 128. DIASOL K1,5G Ca1,25 Ac3          |
| 29. DIASOL K1 Mg1          | 79. DIASOL Na138 K3G Ca1,50 | 129. DIASOL K1,5 Ca1,5 Ac3            |
| 30. DIASOL K1G Mg1         | 80. DIASOL Ac8              | 130. DIASOL K1,5G Ca1,5 Ac3           |
| 31. DIASOL K2 Mg 0,25      | 81. DIASOL K2G Ac3          | 131. DIASOL K1,5 Ca1,75 Ac3           |
| 32. DIASOL K2G Mg 0,25     | 82. DIASOL Ca1,25 Ac5       | 132. DIASOL K1,5G Ca1,75 Ac3          |
| 33. DIASOL K2 Mg 0,25 Ac4  | 83. DIASOL K0               | 133. DIASOL K2Ca1,25 Ac3              |
| 34. DIASOL K2G Mg 0,25 Ac4 | 84. DIASOL Ca1 K1           | 134. DIASOL K2G Ca1,25 Ac3            |
| 35. DIASOL Ca1,25 K1 Ac2   | 85. DIASOL Ca1K1G           | 135. DIASOL K2G Ca1,5 Ac3             |
| 36. DIASOL Ca1,25 K1G Ac2  | 86. DIASOL Ca1,25G Ac5      | 136. DIASOL K2G Ca1,75 Ac3            |
| 37. DIASOL Na140 K3        | 87. DIASOL Na140K1          | 137. DIASOL K1 Ca1,25                 |
| 38. DIASOL Na140 K3G       | 88. DIASOL Ca1,75G Ac5      | 138. DIASOL K1G Ca1,25                |
| 39. DIASOL Ca1,5 K3        | 89. DIASOL Na140 K2 Ac5     | 139. DIASOL K1 Ca1,5                  |
| 40. DIASOL Ca1,5 K3G       | 90. DIASOL Na140 K2G Ac5    | 140. DIASOL K1G Ca1,5                 |
| 41. DIASOL K1 Ca1,75       | 91. DIASOL K2G Ca1,5        | 141. DIASOL K3GCa1.75Ac3              |
| 42. DIASOL K1G Ca1,75      | 92. DIASOL K2 Ca1,75        | 142. DIASOL K2Ca1.75Ac3               |
| 43. DIASOL K1,5 Ca1,25     | 93. DIASOL K2G Ca1,75       | 143. DIASOL Ca1.75K3GAc2              |
| 44. DIASOL K1,5G Ca1,25    | 94. DIASOL K1Ca1.25Ac3      | 144. DIASOL Ca1,75K3Ac2               |
| 45. DIASOL K1,5 Ca1,5      | 95. DIASOL K3Ca1.25Ac3      | 145. DIASOL K 1G(200 mg/dl)           |
| 46. DIASOL K1,5G Ca1,5     | 96. DIASOL K3GCa1.25Ac3     | 146. DIASOL K2G Ac2 (200 mg/dl)       |
| 47. DIASOL K1,5 Ca1,75     | 97. DIASOL K3 Ca1,50 Ac3    | 147. DIASOL Ca1,25 K2G Ac2(200 mg/dl) |
| 48. DIASOL K1,5G Ca1,75    | 98. DIASOL K3G Ca1,50 Ac3   | 148. DIASOL Ca1,5 K3GAc2(200 mg/dl)   |
| 49. DIASOL K2 Ca1,25       | 99. DIASOL K2Ca1.5Ac3       |                                       |
| 50. DIASOL K2G Ca1,25      | 100. DIASOL K3Ca1,75Ac3     |                                       |



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# SZUTEST

**Certificate Number: 2195-MED-1110901**

*Sertifika Numarası*

## **Product Models**

*Ürün Modelleri*

### **3. Powder Acidic Haemodialysis Concentrate**

*Toz Asidik Hemodiyaliz Konsantresi*

- |                           |                            |
|---------------------------|----------------------------|
| 1. DIASOL K1 Ca 1,5 Ac3   | 11. DIASOL Na138 K1 Ca1,5  |
| 2. DIASOL K1G Ca 1,5 Ac3  | 12. DIASOL Na138 K1G Ca1,5 |
| 3. DIASOL K2 Ca 1,25 Ac3  | 13. DIASOL Na138 K2Ca1,25  |
| 4. DIASOL K2G Ca 1,25 Ac3 | 14. DIASOL Na138K2GCa1,25  |
| 5. DIASOL Na140Ac3        | 15. DIASOL Na138K2 Ca1,5   |
| 6. DIASOL K2GCa1,5Ac3     | 16. DIASOL Na138K2GCa1,5   |
| 7. DIASOL Ca1,75Ac3       | 17. DIASOL Na138K2 Ca1,75  |
| 8. DIASOL K2GCa1,75Ac3    | 18. DIASOL Na138K2G Ca1,75 |
| 9. DIASOL K3Ca1,5Ac3      | 19. DIASOL Na138K3 Ca1,5   |
| 10. DIASOL K3GCa1,5Ac3    | 20. DIASOL Na138K3G Ca1,5  |

### **4. Powder Sodium Bicarbonate**

*Toz Sodyum Bikarbonat*

- |                         |                          |                          |
|-------------------------|--------------------------|--------------------------|
| 1. FARMACART B 400      | 11. FARMACART B 450      | 21. FARMACART B 500      |
| 2. FARMACART B 550      | 12. FARMACART B 600      | 22. FARMACART B 650      |
| 3. FARMACART B 700      | 13. FARMACART B 720      | 23. FARMACART B 750      |
| 4. FARMACART B 760      | 14. FARMACART B 800      | 24. FARMACART B 850      |
| 5. FARMACART B 900      | 15. FARMACART B 950      | 25. FARMACART B 1000     |
| 6. FARMACART B 1050     | 16. FARMACART B 1100     | 26. FARMACART B 1150     |
| 7. FARMACART B 1200     | 17. FARMACART B 1250     | 27. FARMACART BAG B 400  |
| 8. FARMACART BAG B 450  | 18. FARMACART BAG B 600  | 28. FARMACART BAG B 650  |
| 9. FARMACART BAG B 720  | 19. FARMACART BAG B 750  | 29. FARMACART BAG B 760  |
| 10. FARMACART BAG B 900 | 20. FARMACART BAG B 1150 | 30. FARMACART BAG B 1200 |
| 1. MEDICART 500         | 11. MEDICART 920         | 21. MEDICART BAG 900     |
| 2. MEDICART 600         | 12. MEDICART 1000        | 22. MEDICART BAG 920     |
| 3. MEDICART 650         | 13. MEDICART 1050        |                          |
| 4. MEDICART 700         | 14. MEDICART 1100        |                          |
| 5. MEDICART 720         | 15. MEDICART 1150        |                          |
| 6. MEDICART 760         | 16. MEDICART 1200        |                          |
| 7. MEDICART 780         | 17. MEDICART 1250        |                          |
| 8. MEDICART 850         | 18. MEDICART BAG 550     |                          |
| 9. MEDICART 860         | 19. MEDICART BAG 650     |                          |
| 10. MEDICART 880        | 20. MEDICART BAG 760     |                          |



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# SZUTEST

**Certificate Number: 2195-MED-1110901**

*Sertifika Numarası*

## **Product Models**

*Ürün Modelleri*

### **5. Haemodialysis Machine Disinfectant**

*Hemodiyaliz Makinası Dezenfektanı*

- |                     |                        |                  |
|---------------------|------------------------|------------------|
| 1. DIADEZ M2,5 L2,5 | 2. DIADEZ C 50         | 3. DIADEZ Cart   |
| 4. DIADEZ PAA       | 5. MEDICADEZ M2,5 L2,5 | 6. MEDICADEZ C50 |

### **6. Sterile Arteriovenous Set and Fistula Needle**

*Steril Arter Ven Seti ve Fistül İğnesi*

#### **Sterile Arteriovenous Set / Steril Arter Ven Seti**

1. DIARENNEEDLE AVS AV 200 (7\*10)
2. DIARENNEEDLE AVS AV 200 T (7\*10)
3. DIARENNEEDLE AVS AV 200 (8\*12)
4. DIARENNEEDLE AVS AV 200 T (8\*12)
5. DIARENNEEDLE AVS AV 201 D (7\*10)
6. DIARENNEEDLE AVS AV 201 D (8\*12)
7. DIARENNEEDLE AVS AV 200 N (8\*12)
8. DIARENNEEDLE AVS AV 202 (8\*12)
9. DIARENNEEDLE AVS AV 203 F 812 T
10. DIARENNEEDLE AVS AV 203 F 812
11. DIARENNEEDLE AVS AV 200 K (7\*10)
12. DIARENNEEDLE AVS AV 200 K (8\*12)
13. DIARENNEEDLE AVS AV 200 KT (7\*10)
14. DIARENNEEDLE AVS AV 200 KT (8\*12)

#### **Sterile Arteriovenous Fistula Needle / Steril Arter Ven Fistül İğnesi**

1. DIARENNEEDLE AVF 15G AR
2. DIARENNEEDLE AVF 15G VR
3. DIARENNEEDLE AVF 16G AR
4. DIARENNEEDLE AVF 16G VR
5. DIARENNEEDLE AVF 16G AF
6. DIARENNEEDLE AVF 16G VF
7. DIARENNEEDLE AVF 17G AR
8. DIARENNEEDLE AVF 17G VR



**SZUTEST UYGUNLUK DEĞERLENDİRME A.Ş.**

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