

akssert

# CERTIFICATE

Ayset Tıbbi Ürünler ve Plastik Tekstil  
Elektronik Gıda Temizlik Maddeleri İnşaat  
Müteahhitlik Sanayi Anonim Şirketi

Sarıhamzalı Mahallesi 47007 Sokak No:36/A Seyhan ADANA / TURKEY

## ISO 13485:2016

Scope: Production, sales and marketing Medical disposable products; injection, infusion and transfusion devices

Hereby, AKSSERT Audit and Certification Ltd. Co., certifies that the above stated company gave the appropriate management system according to the requirements of the above standard. This certificate valid for 3 years since the decision date as long as the system is effectively maintained and surveillance audits are carried out. The validity of certificate can be checked through [www.akssert.com](http://www.akssert.com), [www.jas-anz.org/register](http://www.jas-anz.org/register). The Certificate is property of AKSSERT Audit and Certification Ltd. Co. and shall be returned if requested.

The reference standard is ISO 13485:2016



AKSSERT Audit and  
Certification Ltd. Co.



Certificate Number : 85228  
Registration Date : 30.01.2015

Reissue Date : 29.01.2021  
Expiry Date : 28.01.2024

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AYSET TIBBİ ÜRÜNLER VE PLASTİK TEKSTİL  
ELEKTRONİK GIDA TEMİZLİK MADDELERİ  
İNŞAAT MÜTEAHHİTLİK SAN. A.Ş.  
Sarıhamzalı Mah. 47007 Sk No:36/A Seyhan  
Adana, TURKEY

D18-07

**European Declaration of Conformity  
to the Medical Device For IVD Directive, 98/79/EEC**



**Product Name** : Vacuum Blood Collection Tubes  
**Description** : Single use containers for human venous blood specimen  
**Sterile** : Yes  
**Classification / Rule** : IVD Other  
**GMDN Code** : 35414  
**Conformity Assessment Route** : Annex III of IVD 98/79 EC  
**Applicable Standards** : EN ISO 14820, EN ISO 15223-1, EN ISO 14971, EN ISO 18113-3

**Declaration :**

AYSET TIBBİ ÜRÜNLER VE PLASTİK TEKSTİL ELEKTRONİK GIDA TEMİZLİK MADDELERİ İNŞAAT MÜTEAHHİTLİK SAN. A.Ş. declares that the above products related to this declaration, bears the CE marking and it meet the essential provisions of the European Parliament and of the Council Directive 98/79/EC of 27 October 1998 concerning **in vitro diagnostic medical devices** which apply to them and have a free distribution, sale and circulation of in the member of EU.

All supporting documentation is retained at the manufacturer's premises.

The present EC Declaration of Conformity is applicable to all mentioned medical devices, manufactured by AYSET TIBBİ ÜRÜNLER VE PLASTİK TEKSTİL ELEKTRONİK GIDA TEMİZLİK MADDELERİ İNŞAAT MÜTEAHHİTLİK SAN. A.Ş. Adana, TURKEY, and/or anyway controlled under the Manufacturer's Certified Quality Control System for approximately 1 year from the approval date of the present document.

Start of CE Certificate : 30 May 2011

AYSET TIBBİ ÜRÜNLER VE PLASTİK TEKSTİL ELEKTRONİK GIDA TEMİZLİK MADDELERİ İNŞAAT MÜTEAHHİTLİK SAN. A.Ş.

Date : 13 August 2021

Signature

**YILMAZ AYTEKİN**

AYSET General Manager



## LIST OF PRODUCTS

|     | Ref No | Product Description                         |
|-----|--------|---------------------------------------------|
| 1.  | 70651  | Vacuum Tube 13x75 No Additive 4ml           |
| 2.  | 70652  | Vacuum Tube 13x100 No Additive 6ml          |
| 3.  | 70653  | Vacuum Tube 16x100 No Additive 9ml          |
| 4.  | 70654  | Vacuum Tube 13x75 Clot Activator 4ml        |
| 5.  | 70655  | Vacuum Tube 13x100 Clot Activator 6ml       |
| 6.  | 70656  | Vacuum Tube 16x100 Clot Activator 9ml       |
| 7.  | 70657  | Vacuum Tube 13x75 Gel&Clot Activator 3,5ml  |
| 8.  | 70658  | Vacuum Tube 13x100 Gel&Clot Activator 5ml   |
| 9.  | 70659  | Vacuum Tube 16x100 Gel&Clot Activator 8,5ml |
| 10. | 70660  | Vacuum Tube 13x75 EDTA K2E 2ml              |
| 11. | 70661  | Vacuum Tube 13x75 EDTA K2E 4ml              |
| 12. | 70662  | Vacuum Tube 13x75 EDTA K2E+Gel 4ml          |
| 13. | 70663  | Vacuum Tube 16x100 EDTA K2E+Gel 9ml         |
| 14. | 70664  | Vacuum Tube 13x75 EDTA K3E 2ml              |
| 15. | 70665  | Vacuum Tube 13x75 EDTA K3E 4ml              |
| 16. | 70666  | Vacuum Tube 13x75 Lithium Heparin 4ml       |
| 17. | 70667  | Vacuum Tube 13x100 Lithium Heparin 6ml      |
| 18. | 70668  | Vacuum Tube 16x100 Lithium Heparin 9ml      |
| 19. | 70669  | Vacuum Tube 13x75 Lithium Heparin+Gel 4ml   |
| 20. | 70670  | Vacuum Tube 16x100 Lithium Heparin+Gel 9ml  |
| 21. | 70671  | Vacuum Tube 13x75 Sodium Heparin 3ml        |
| 22. | 70672  | Vacuum Tube 13x100 Sodium Heparin 5ml       |
| 23. | 70673  | Vacuum Tube 16x100 Sodium Heparin 8ml       |
| 24. | 70674  | Vacuum Tube 13x75 Fluoride Oxalate 2ml      |
| 25. | 70675  | Vacuum Tube 13x75 Fluoride Oxalate 3ml      |
| 26. | 70676  | Vacuum Tube 13x75 9NC Sodium Citrate 2,7ml  |
| 27. | 70677  | Vacuum Tube 13x75 9NC Sodium Citrate 1,8ml  |
| 28. | 70678  | Vacuum Tube 13x75 4NC Sodium Citrate 1,6ml  |
| 29. | 70679  | Vacuum Tube 13x75 4NC Sodium Citrate 1,8ml  |
| 30. | 70680  | Vacuum Tube 9x120 4NC Sodium Citrate 1,6ml  |
| 31. | 70681  | Vacuum Tube 13x75 Lithium Heparin 2ml       |
| 32. | 70683  | Vacuum Tube 13x75 Lithium Heparin 2,7ml     |
| 33. | 70684  | Vacuum Tube 13x75 4NC Sodium Citrate 2,5ml  |
| 34. | 70685  | Vacuum Tube 13x75 EDTA K2E 3ml              |
| 35. | 70686  | Vacuum Tube 13x75 Gel&Clot Activator 4ml    |
| 36. | 70687  | Vacuum Tube 13x75 EDTA K3E 1ml              |
| 37. | 70692  | Vacuum Tube 13x100 Clot Activator 5ml       |
| 38. | 70693  | Vacuum Tube 16x100 No Additive 9ml          |
| 39. | 70694  | Vacuum Tube 13x75 4NC Sodium Citrate 2,4ml  |
| 40. | 70695  | Vacuum Tube 8x120 4NC Sodium Citrate 1,6ml  |
| 41. | 70696  | Vacuum Tube 13x75 Sodium Flouride+EDTA 2ml  |
| 42. | 70697  | Vacuum Tube 13x75 EDTA K3E 3ml              |
| 43. | 70698  | Vacuum Tube 13x75 9NC Sodium Citrate 2,5ml  |
| 44. | 70699  | Vacuum Tube 16x100 EDTA K3E 9ml             |
| 45. | 70700  | Vacuum Tube 13x75 9NC Sodium Citrate 2ml    |
| 46. | 70701  | Vacuum Tube 16x100 No Additive 10ml         |

|     |       |                                                  |
|-----|-------|--------------------------------------------------|
| 47. | 70702 | Vacuum Tube 16x100 Clot Activator 10ml           |
| 48. | 70711 | Vacuum Tube 13x75 Fluoride Oxalate 4ml           |
| 49. | 70712 | Vacuum Tube 13x75 9NC Sodium Citrate 4ml         |
| 50. | 70714 | Vacuum Tube 13x75 9NC Sodium Citrate 3,6ml       |
| 51. | 70716 | Vacuum Tube 13x100 EDTA K3E 5ml                  |
| 52. | 70719 | Vacuum Tube 13x100 Lithium Heparin+Gel 5ml       |
| 53. | 70722 | Vacuum Tube 13x75 9NC Sodium Citrate 4,5ml       |
| 54. | 70723 | Vacuum Tube 16x100 Gel&Clot Activator 6ml        |
| 55. | 70725 | Vacuum Tube 13x100 Eser Element 6ml              |
| 56. | 70726 | Vacuum Tube 16x100 Gel&Clot Activator 8ml        |
| 57. | 70727 | Vacuum Tube 13x100 Lithium Heparin 5ml           |
| 58. | 70728 | Vacuum Tube 13x100 No Additive 5ml               |
| 59. | 70729 | Vacuum Tube 13x75 Sodium Flouride+EDTA K3E 3ml   |
| 60. | 70730 | Vacuum Tube 13x100 EDTA K3E 6ml                  |
| 61. | 70747 | Vacuum Tube 16x100 Clot Activator 8ml            |
| 62. | 70748 | Vacuum Tube 13x75 4NC Sodium Citrate 2ml         |
| 63. | 70754 | Vacuum Tube 13x75 Sodium Flouride+EDTA K3E 2ml   |
| 64. | 70755 | Vacuum Tube 16x100 No Additive 8,5ml             |
| 65. | 70756 | Vacuum Tube 13x75 No Additive 2ml                |
| 66. | 70757 | Vacuum Tube 16x100 EDTA K3E 7ml                  |
| 67. | 70758 | Vacuum Tube 13x100 Gel&Clot Activator 5,5ml      |
| 68. | 70059 | Vacuum Tube 13x75 Gel&Clot Activator 3ml         |
| 69. | 70060 | Vacuum Tube 13x75 9NC Sodium Citrate 3,8% 1,8ml  |
| 70. | 70062 | Vacuum Tube 13x75 Sodium Flouride+EDTA K2E 2ml   |
| 71. | 70063 | Vacuum Tube 13x75 Sodium Flouride+EDTA K2E 3ml   |
| 72. | 70069 | Vacuum Tube 13x75 Lithium Heparin 3ml            |
| 73. | 70070 | Vacuum Tube 16x100 Gel&Clot Activator 9ml        |
| 74. | 70071 | Vacuum Tube 13x75 Gel&Clot Activator 2ml         |
| 75. | 70480 | Vacuum Tube 16x100 No Additive 8,5ml             |
| 76. | 70487 | Vacuum Tube 13x75 EDTA K3E 4,5ml                 |
| 77. | 81032 | Vacuum Tube 13x100 EDTA K2E 6ml                  |
| 78. | 81033 | Vacuum Tube 13x75 9NC Sodium Citrate 3,8% 3ml    |
| 79. | 81047 | Vacuum Tube 13x75 9NC Sodium Citrate 3ml         |
| 80. | 81141 | Vacuum Tube 13x75 Lithium Heparin+Gel 3ml        |
| 81. | 81142 | Vacuum Tube 13x75 4NC Sodium Citrate 2,4ml       |
| 82. | 81184 | Vacuum Tube 16x100 EDTA K2E 9ml                  |
| 83. | 81185 | Vacuum Tube 13x75 Clot Activator 3ml             |
| 84. | 81201 | Vacuum Tube 13x75 9NC Sodium Citrate 3,8% 3,6ml  |
| 85. | 81202 | Vacuum Tube 13x75 9NC Sodium Citrate 3,8% 2,7ml  |
| 86. | 81282 | Vacuum Tube 13x100 9NC Sodium Citrate 3,8% 4,5ml |





# EC CERTIFICATE

## Production Quality Assurance Medical Devices Directive 93/42/EEC Annex V

Company Name : Ayset Tıbbi Ürünler ve Plastik Tekstil Elektronik Gıda Temizlik Maddeleri İnşaat Mühendislik San. A.Ş.

Company Address : Sarıhamzalı Mah. 47007 Sokak No:36/A Seyhan ADANA / TURKEY

Related Directives and Annex : 93/42/EEC Medical Devices Directive - Annex V

Product :  
- Sterile, Single Use 3 Pieces Arterial blood gas sampler with needle - Class IIa  
- Sterile, Single Use 3 Pieces Syringes (Without Needle, Luer Slip/ Luer Lock) - Class Is  
- Sterile, Single Use 2 Pieces Syringes (Without Needle, Luer Slip/ Luer Lock) - Class Is  
- Sterile, Single Use 3 Pieces Syringes (With Needle, Luer Slip/ Luer Lock) - Class IIa  
- Sterile, Single Use 2 Pieces Syringes (With Needle, Luer Slip/ Luer Lock) - Class IIa  
- Sterile, Single Use U-100 Insulin Syringes (Without Needle) - Class Is  
- Sterile, Single Use U-100 Insulin Syringes (With Needle) - Class IIa  
- Sterile, Single Use Tuberculin Syringes (Without Needle) - Class Is  
- Sterile, Single Use Tuberculin Syringes (With Needle) - Class IIa  
- Sterile, Single Use Hypodermic Needles - Class IIa  
- Sterile, Single Use Multi-Sample Blood Collection Needles - Class IIa  
- Sterile, Single Use Multi-Sample Blood Collection Needles Butterfly Set Type - Class IIa  
- Sterile, Single Use Insulin Pen Injector Needles - Class IIa

GMDN : 58095, 35904, 34973, 38501, 32592, 59230, 35209

Certificate Number : M.2016.106.6922

Report Number : MD.3205.YB

Initial Assessment Date : 16.07.2016

Registration Date : 06.08.2016

Recertification Assessment Date : 09.12.2020

Reissue Date / No : 25.05.2021/01

Revision Date /No : -

Expiry Date : 27.05.2024



UDEM International Certification  
Auditing Training Centre Industry  
and Trade Inc. Co.

UDEM hereby declares that the requirements of Annex V of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance audits, defined by Annex V, section 4 of the aforementioned directive. UDEM's responsibility for class I devices covered by the EC certificate is limited to manufacturing issues related to safeguarding and maintaining sterile conditions, if the device is sterile; and manufacturing issues related to product's conformity with metrological requirements, if it has measurement function. This certificate remains as the property of UDEM International Certification Auditing Training Centre Industry and Trade Inc. Co. to whom it must be returned upon request. The above named company and UDEM must keep a copy of this certificate for 5 years from the registration of the certificate. Usage of the CE mark is under the responsibility of the manufacturer with the completion of EC Declaration of Conformity. The above mentioned company must notify all changes related with the approved product to UDEM. If UDEM will not renew the expiry date of this certificate in question, the mentioned company should stop placing the product on the market. The validity of the certificate can be checked through [www.udem.com.tr](http://www.udem.com.tr).



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