Digitally signed by Granaci Boris
Date: 2024.01.11 15:23:46 EET
Reason: MoldSign Signature
Location: Moldova

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., certificates 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 maintaned and surveillance audits are carried out. The validity of certificate can be checked through www.akssert.com, 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

Address: Mustafa Kemal Mah. 2157/1 Sokak No:5/7 Çankaya / ANKARA– TÜRKİYE
Phone: +90 312 284 99 44(pbx)
E-mail: info@akssert.com **Web:** www.akssert.com

Manufacturer:

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

Document id – Rev. Number:

D18-07

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

CE

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 MÜTEAAHHİTLİK 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 MÜTEAAHHİTLİK 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 MÜTEAAHHİTLİK 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 Müteahhitlik 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 Neddles - 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 sertificate is limited to manufacturing issues related to safeguarding and maintaining sterile conditions, if the dev,ce 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.

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