Anexa nr. 1
La Procedurile administrative pentru notificarea dispozitivelor medicale care deţin marcajul CE

Către Agenţia Medicamentului
şi Dispozitivelor Medicale

NOTIFICARE
pentru înregistrarea dispozitivelor medicale în Registrul de stat
al dispozitivelor medicale
nr. 05 din 06.07.2023

Solicitantul **„MedGlobalFarm" SRL**, cu sediul **R.Moldova, mun.Chisinau, str.Miron Costin 17/7, of.71**, tel./fax: 022-523090, e-mail medglobalfarm@mail.ru, solicit înregistrarea în Registrul de stat al dispozitivelor medicale a următoarelor categorii şi tipuri de dispozitive medicale pentru introducerea şi punerea la dispoziţie pe piaţă a:

Nr.	Numărul de catalog (referinţă)*	Denumire generică (denumirea dispozitivului)	Denumire comercială (brand)*	Modelul	Cod GMDN*
1	70676	Eprubetă cu citrat de natriu 3.2% 2,7 ml	Test tube with sodium citrate 3.2% 2,7 ml		47783
2	70654	Eprubeta cu clod activator, 4ml, cu eticheta 10x75mm	Test tube with clod activator, 4ml, with label 10x75mm		47783
3	70687	Eprubete (K3EDTA) volum de singe 1 ml 13x75 mm	Test tubes (K3EDTA) blood volume 1 ml 13x75 mm		47783
4	70665	Eprubete (K3EDTA). Volum de singe 4 ml	Test tubes (K3EDTA). blood volume 4 ml		47783
5	70716	Eprubete (K3EDTA) volum de singe 5 ml. 13x100 mm	Test tubes (K3EDTA). blood volume 5 ml. 13x100 mm		47783
6	70684	Eprubeta vacumată cu citrate de sodiu 3.8%. volum sânge 2.5 ml	Vacuum test tube with sodium citrate 3.8%. blood volume 2.5 ml		47783
7	70656	Eprubeta sterilă Lyiet. volumul 9 ml	Sterile test tube Lyiet. volume 9 ml		47783
8	70664	Eprubete (K3EDTA). Volum de singe 2.0 ml	Test tubes (K3EDTA) blood volume 2.0 ml		47783
9	70697	Eprubete (K3EDTA). Volum de singe 3 ml 13x75 mm	Test tubes (K3EDTA) blood volume 3 ml 13x75 mm		47783
10	70699	Eprubete (K3EDTA). Volum de singe 9 ml	Test tubes (K3EDTA). blood volume 9 ml		47783

Se anexează următoarele acte:

declaraţia de conformitate CE emisă de producător pentru dispozitivul medical fabricat;
certificatul de conformitate CE valabil pentru dispozitivele fabricate;

Digitally signed by Granaci Boris
Date: 2023.10.13 13:28:56 EEST
Reason: MoldSign Signature
Location: Moldova

S.R.L. «MEDGLOBALFARM» IDNO 1016600000765

actul prin care producătorul își desemnează reprezentantul/

Data 08.08.2023

Semnătura _____

Tabelul de recepționare a notificării

(se completează de către Agenție în momentul depunerii notificării de către solicitant)

Comentarii cu privire la acceptul/refuzul recepționării notificării, inclusiv motivul refuzului	
Data/nr. de ordine atribuit notificării de către Agenție (în cazul acceptării recepționării)	
Numele, prenumele, funcția persoanei responsabile de recepționarea dosarului	
Semnătura persoanei responsabile	

SOCIETATEA CU RĂSPUNDERE LIMITATĂ
S.R.L.
„MEDGLOBALFARM"
IDNO 1016600000765
REPUBLICA MOLDOVA

Manufacturer:	*Individual Identification Number (SRN):*	Document id – Rev. Number:
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	TR-MF-000016409	D18-08

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
Conformity Assessment Route	: Annex III of IVD 98/79 EC
Applicable Standards	: EN ISO 6710, EN ISO 15223-1, EN ISO 14971

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 : 18 May 2022
Signature

YILMAZ AYTEKİN
AYSET General Manager

S.R.L. «MEDGLOBALFARM» IDNO 1016600000765 REPUBLICA MOLDOVA

LIST OF PRODUCTS

	Ref No	Description of the Product	GMDN CODE
1.	70651	Vacuum Tube 13x75 No Additive 4ml	47590
2.	70652	Vacuum Tube 13x100 No Additive 6ml	47590
3.	70653	Vacuum Tube 16x100 No Additive 9ml	47590
4.	70654	Vacuum Tube 13x75 Clot Activator 4ml	42386
5.	70655	Vacuum Tube 13x100 Clot Activator 6ml	42386
6.	70656	Vacuum Tube 16x100 Clot Activator 9ml	42386
7.	70657	Vacuum Tube 13x75 Gel&Clot Activator 3,5ml	41128
8.	70658	Vacuum Tube 13x100 Gel&Clot Activator 5ml	41128
9.	70659	Vacuum Tube 16x100 Gel&Clot Activator 8,5ml	41128
10.	70660	Vacuum Tube 13x75 EDTA K2E 2ml	43865
11.	70661	Vacuum Tube 13x75 EDTA K2E 4ml	43865
12.	70662	Vacuum Tube 13x75 EDTA K2E+Gel 4ml	47587
13.	70663	Vacuum Tube 16x100 EDTA K2E+Gel 9ml	47587
14.	70664	Vacuum Tube 13x75 EDTA K3E 2ml	47588
15.	70665	Vacuum Tube 13x75 EDTA K3E 4ml	47588
16.	70666	Vacuum Tube 13x75 Lithium Heparin 4ml	47589
17.	70667	Vacuum Tube 13x100 Lithium Heparin 6ml	47589
18.	70668	Vacuum Tube 16x100 Lithium Heparin 9ml	47589
19.	70669	Vacuum Tube 13x75 Lithium Heparin+Gel 4ml	46054
20.	70670	Vacuum Tube 16x100 Lithium Heparin+Gel 9ml	46054
21.	70671	Vacuum Tube 13x75 Sodium Heparin 3ml	47592
22.	70672	Vacuum Tube 13x100 Sodium Heparin 5ml	47592
23.	70673	Vacuum Tube 16x100 Sodium Heparin 8ml	47592
24.	70674	Vacuum Tube 13x75 Fluoride Oxalate 2ml	47591
25.	70675	Vacuum Tube 13x75 Fluoride Oxalate 3ml	47591
26.	70676	Vacuum Tube 13x75 9NC Sodium Citrate 2,7ml	42585
27.	70677	Vacuum Tube 13x75 9NC Sodium Citrate 1,8ml	42585
28.	70678	Vacuum Tube 13x75 4NC Sodium Citrate 1,6ml	42585
29.	70679	Vacuum Tube 13x75 4NC Sodium Citrate 1,8ml	42585
30.	70680	Vacuum Tube 9x120 4NC Sodium Citrate 1,6ml	42585
31.	70681	Vacuum Tube 13x75 Lithium Heparin 2ml	47589
32.	70683	Vacuum Tube 13x75 Lithium Heparin 2,7ml	47589
33.	70684	Vacuum Tube 13x75 4NC Sodium Citrate 2,5ml	42585
34.	70685	Vacuum Tube 13x75 EDTA K2E 3ml	47588
35.	70686	Vacuum Tube 13x75 Gel&Clot Activator 4ml	41128
36.	70687	Vacuum Tube 13x75 EDTA K3E 1ml	47588
37.	70692	Vacuum Tube 13x100 Clot Activator 5ml	42386
38.	70693	Vacuum Tube 16x100 No Additive 9ml	47590
39.	70694	Vacuum Tube 13x75 4NC Sodium Citrate 2,4ml	42585
40.	70695	Vacuum Tube 8x120 4NC Sodium Citrate 1,6ml	42585
41.	70696	Vacuum Tube 13x75 Sodium Flouride+EDTA 2ml	45805
42.	70697	Vacuum Tube 13x75 EDTA K3E 3ml	47588
43.	70698	Vacuum Tube 13x75 9NC Sodium Citrate 2,5ml	42585
44.	70699	Vacuum Tube 16x100 EDTA K3E 9ml	47588
45.	70700	Vacuum Tube 13x75 9NC Sodium Citrate 2ml	42585
46.	70701	Vacuum Tube 16x100 No Additive 10ml	47590

47.	70702	Vacuum Tube 16x100 Clot Activator 10ml	42386
48.	70711	Vacuum Tube 13x75 Fluoride Oxalate 4ml	47591
49.	70712	Vacuum Tube 13x75 9NC Sodium Citrate 4ml	42585
50.	70714	Vacuum Tube 13x75 9NC Sodium Citrate 3,6ml	42585
51.	70716	Vacuum Tube 13x100 EDTA K3E 5ml	47588
52.	70719	Vacuum Tube 13x100 Lithium Heparin+Gel 5ml	46054
53.	70722	Vacuum Tube 13x75 9NC Sodium Citrate 4,5ml	42585
54.	70723	Vacuum Tube 16x100 Gel&Clot Activator 6ml	41128
55.	70726	Vacuum Tube 16x100 Gel&Clot Activator 8ml	41128
56.	70727	Vacuum Tube 13x100 Lithium Heparin 5ml	47589
57.	70728	Vacuum Tube 13x100 No Additive 5ml	47590
58.	70729	Vacuum Tube 13x75 Sodium Flouride+EDTA K3E 3ml	58090
59.	70730	Vacuum Tube 13x100 EDTA K3E 6ml	47588
60.	70734	Vacuumed Urine Container	58158
61.	70747	Vacuum Tube 16x100 Clot Activator 8ml	42386
62.	70748	Vacuum Tube 13x75 4NC Sodium Citrate 2ml	42585
63.	70754	Vacuum Tube 13x75 Sodium Flouride+EDTA K3E 2ml	58090
64.	70755	Vacuum Tube 16x100 No Additive 8,5ml	47590
65.	70756	Vacuum Tube 13x75 No Additive 2ml	47590
66.	70757	Vacuum Tube 16x100 EDTA K3E 7ml	47588
67.	70758	Vacuum Tube 13x100 Gel&Clot Activator 5,5ml	41128
68.	70059	Vacuum Tube 13x75 Gel&Clot Activator 3ml	41128
69.	70060	Vacuum Tube 13x75 9NC Sodium Citrate 3,8% 1,8ml	42585
70.	70062	Vacuum Tube 13x75 Sodium Flouride+EDTA K2E 2ml	44488
71.	70063	Vacuum Tube 13x75 Sodium Flouride+EDTA K2E 3ml	44488
72.	70069	Vacuum Tube 13x75 Lithium Heparin 3ml	47589
73.	70070	Vacuum Tube 16x100 Gel&Clot Activator 9ml	41128
74.	70071	Vacuum Tube 13x75 Gel&Clot Activator 2ml	41128
75.	70480	Vacuum Tube 16x100 No Additive 8,5ml	47590
76.	70487	Vacuum Tube 13x75 EDTA K3E 4,5ml	47588
77.	81032	Vacuum Tube 13x100 EDTA K2E 6ml	43865
78.	81033	Vacuum Tube 13x75 9NC Sodium Citrate 3,8% 3ml	42585
79.	81047	Vacuum Tube 13x75 9NC Sodium Citrate 3ml	42585
80.	81141	Vacuum Tube 13x75 Lithium Heparin+Gel 3ml	46054
81.	81142	Vacuum Tube 13x75 4NC Sodium Citrate 2,4ml	42585
82.	81184	Vacuum Tube 16x100 EDTA K2E 9ml	43865
83.	81185	Vacuum Tube 13x75 Clot Activator 3ml	42386
84.	81201	Vacuum Tube 13x75 9NC Sodium Citrate 3,8% 3,6ml	42585
85.	81202	Vacuum Tube 13x75 9NC Sodium Citrate 3,8% 2,7ml	42585
86.	81282	Vacuum Tube 13x100 9NC Sodium Citrate 3,8% 4,5ml	42585
87.	81241	Vacuum Tube 16x100 Gel&Clot Activator 6,5ml	41128
88.	81245	Vacuum Tube 13x100 9NC Sodium Citrate 3,2% 5ml	42585
89.	81274	Vacuum Tube 13x75 Sodium Heparin 4ml	47592
90.	81285	Vacuum Tube 13x75 Clot Activator 2ml	42386
91.	81286	Vacuum Tube 13x75 Clot Activator 3,5ml	42386
92.	81289	Vacuum Tube 13x75 9NC Sodium Citrate 1ml	42585
93.	81297	16x100 Urine Tubes with Chlorhexidine 8ml	57924
94.	81298	16x100 Urine Tubes with Chlorhexidine 10ml	57924
95.	81531	16X100 Vacuum Tube Lithium Heparin+Gel 8ml	46054

S.R.L. «MEDGLOBALFARM» IDNO 1016600000765 REPUBLICA MOLDOVA

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.

Address: Mutlukent Mahallesi 2073 Sokak (Eski 93 Sokak) No:10 Çankaya – Ankara – TURKEY
Phone: +90 0312 443 03 90 **Fax:** +90 0312 443 03 76
E-mail: info@udemltd.com.tr www.udem.com.tr

AYSET
Tıbbi Ürünler

28 July, 2023

TO WHOM IT MAY CONCERN

LETTER OF AUTHORIZATION

We declare that **MED GLOBALFARM SRL** located at adress below:

Str. Miron Costin 17 / 7 of. 71, Chisinau, 2068 MOLDOVA

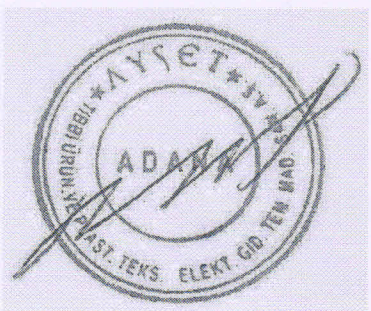
is our agent and authorized to import the products from **Ayset Tıbbi Ürünler ve Tekstil Elektronik Gida Temizlik Maddeleri Insaat Muteahhitlik San. A.Ş.** located at **Sarıhamzalı Mah. 47007 Sk. No:36/A Seyhan, Adana, TURKIYE**

in Moldova Territory.

In addition, we hereby authorize **MED GLOBALFARM SRL** to register our products in the Republic of Moldova.

This authorization letter is effective from July 28th, 2023 and will be valid until July 28th, 2024.

Best regards,



Ayset Tıbbi Ürünler San. A.Ş.

AYSET TIBBİ ÜRÜNLER SAN. A.Ş.
Sarıhamzalı Mah. 47007 Sk. No:36/A Seyhan / Adana / TÜRKİYE
Tel: +90 (322) 441 12 99 Fax: +90 (322) 441 12 98 e-mail:info@ayset.com web:www.ayset.com

Anexa nr. 2
La Procedurile administrative pentru notificarea dispozitivelor medicale care deţin marcajul CE

Către Agenţia Medicamentului şi Dispozitive Medicale

DECLARAŢIE PE PROPRIE RĂSPUNDERE

Solicitant: Medglobalfarm SRL, cu sediul mun. Chişinău,str.Miron Costin 14 ,

declar pe proprie răspundere, cunoscând prevederile art. **352[1]**, Codul Penal al Republicii Moldova cu privire la falsul în declaraţii, că documentele şi datele furnizate pentru notificarea dispozitivului medical:

1. declaraţia de conformitate CE emisă de producător pentru dispozitivul medical fabricat ;
2. certificatul de conformitate CE valabil pentru dispozitivele fabricate
3. actul prin care producătorul îşi desemnează reprezentantul;

Sunt autentice şi corespund realităţii.

Numele, prenumele şi funcţia SOCIETATEA CU RĂSPUNDERE LIMITATĂ S.R.L. «MEDGLOBALFARM» IDNO 1016600000765 REPUBLICA MOLDOVA mun. CHIŞINĂU *Semnătura* _____

Data 08.08.2023