

Către Agenția Medicamentului și Dispozitivelor Medicale

NOTIFICARE

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

Solicitantul **Dita Estfarm SRL**, cu sediul **str-la Burebistra 23, MD-2032, Chisinau, Republica Moldova**, tel./fax: **022 782 875**, e-mail: **irina.sandu@dita.md** solicit
înregistrarea în Registrul de stat al dispozitivelor medicale a următoarelor categorii și tipuri
de dispozitive medicale pentru introducerea și punerea la dispoziție pe piață a
producătorului **AYSET TIBBI URUNLER VE PLASTIK TEKSTIL ELEKTRONIK GIDA
TEMIZLIK MADDELERI SAN. A.S., Turcia:**

- Seringă 50ml fără ac
- ~~Seringă 50ml cu ac~~

sanche

Se anexează următoarele acte:

- Actul de reprezentanță între producător și reprezentantul autorizat în Republica Moldova;
- Declarația de conformitate CE;
- Certificat de conformitate CE;
- Declarația pe propria răspundere a solicitantului;
- Lista dispozitivelor medicale (format Excel).

Data **07.09.2023**

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	<i>Accept</i>
Data/nr. de ordine atribuit notificării de către Agenție (în cazul acceptării recepționării)	<i>No. 7354 din 11.09.2023</i>
Numele, prenumele, funcția persoanei responsabile de recepționarea dosarului	<i>Clavatechi Doiniță</i>
Semnătura persoanei responsabile	<i>CDJ</i>

Către Agenția Medicamentului și Dispozitive Medicale

DECLARAȚIE PE PROPRIE RĂSPUNDERE

Solicitant: **Dita Estfarm SRL**, cu sediul **str-la Burebistra 23, MD-2032,**
Chisinau, Republica Moldova,

declar pe proprie răspundere, cunoscând prevederile art. 352¹, Codul Penal al Republicii Moldova cu privire la falsul în declarații, că documentele și datele furnizate pentru notificarea dispozitivelor medicale ale producătorului producătorului **AYSET TIBBI URUNLER VE PLASTIK TEKSTIL ELEKTRONIK GIDA TEMIZLIK MADDELERI SAN. A.S., Turcia:**

- Seringă 50ml fără ac
- Seringă 50ml cu ac

Sunt autentice și corespund realității.

Numele, prenumele și funcția:

RA-Manager – Sandu Irina

Semnătura _____



Data 07.09.2023

We, Ayset Tıbbi Ürünler ve Plastik Tekstil Elektronik Gıda Temizlik Maddeleri İnşaat Müteahhitlik San. A.Ş, based in Sarıhamzalı Mah. 47007 Sk. No:36/A Seyhan, Adana, TURKEY, assign Dita Estfarm LLC, based in No.23 Burebista street, Chisinau MD -2032, Republic of Moldova, as authorized representative in correspondence with the conditions if directive 93/42/EEC.

We declare that the company mentioned above is authorized to register, notify, renew or modify the registration of medical devices on the territory of the Republic of Moldova.

Place: Adana, TURKEY

Date: 18.08.2021

Signed: _____





EC CERTIFICATE

Production Quality Assurance

Medical Devices Directive 93/42/EEC Annex V

Company Name : Ayset Tibbi Ürünler ve Plastik Tekstil Elektronik Gıda Temizlik Maddeleri İnşaat MÜteahhiflik 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



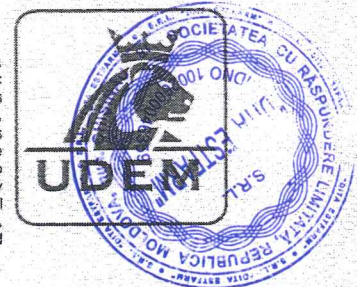
UDEM International Certification
Auditing Training Centre Industry
and Trade Inc. Co.

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.

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

D47-01

European Declaration of Conformity to the Medical Device Directive, 93/42/EEC



Product Name	: Syringes without needle
Description	: Syringes are sterile, disposable, manufactured from plastic material, without needle, 2 parts or 3 parts
Intended Use	: Disposable Syringes are used for aspiration of body fluids and injection fluid medicines.
Sterile	: Yes
Classification (acc. to MDD)	: Class I - S / Rule 6
GMDN Code	: 35904
Conformity	: Annex V
Related	: EN ISO 7886-1, EN ISO 7864, EN ISO 14971, EN ISO 11135, EN ISO 13485, EN ISO 15223-1, EN ISO 10993-1, EN ISO 556-1, EN ISO 14644, EN ISO 14644-3, EN ISO 11607-1, EN ISO 11607-2
Product Declaration :	: Look at the second page

1. AYSET TIBBİ ÜRÜNLER VE PLASTİK TEKSTİL ELEKTRONİK GIDA TEMİZLİK

MÜTEAHHİTLİK SAN. A.Ş. declares that the above product, to which this declaration relates, bears the CE marking and is in conformity with the applicable requirements of the Council Directive MDD 93/42/EEC of 14 June 1993, concerning medical devices, which allows its free distribution, sale and circulation in EEC.

2. As required by the above mentioned Directive, this Declaration is supported by;

EC Certificate No	: M.2016.106.6922
QSys Certificate No	: TC-75581
Notified Body	: UDEM INTERNATIONAL CERTIFICATION AUDITING TRAINING CENTER INDUSTRY AND TRADE INC. CO (id. #2292)

AYSET TIBBİ ÜRÜNLER VE PLASTİK TEKSTİL ELEKTRONİK GIDA TEMİZLİK MADDELERİ İNŞAAT MÜTEAHHİTLİK SAN. A.Ş. Commits to fulfill the requirement of the approved quality system, to maintain quality system completely and effectively, to review the data obtained from medical devices after production, including provision of Annex X, to establish a system for implementation of necessary corrective actions and to keep this system updated. 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 realized under the Manufacturer's Certified Quality System control for a period of about 1 year from the approval date of the present document.

Start Date of CE Mark : 25 MAY 2021

Validity : 27 MAY 2024

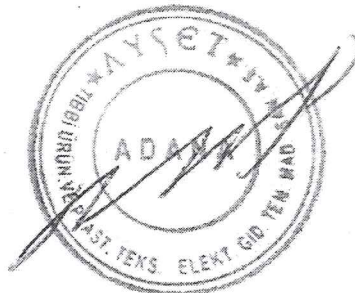
AYSET TIBBİ ÜRÜNLER VE PLASTİK TEKSTİL ELEKTRONİK GIDA TEMİZLİK MADDELERİ İNŞAAT MÜTEAHHİTLİK SAN. A.Ş.

Date : 25.05.2021

Signature

YILMAZ AYTEKİN

AYSET General Manager



Individual Packaging Barcode	Brand Name	Description of Goods	Ref. No	GMDN Code
8697427700198	AYSET	3 PARTS 50ML SYRINGE WITHOUT NEEDLE	70061	35904 - Metered-delivery hypodermic syringe
8697427708217	AYSET	2 PARTS 5ML SYRINGE WITHOUT NEEDLE	70555	35904 - Metered-delivery hypodermic syringe
8697427708286	AYSET	2 PARTS 10ML SYRINGE WITHOUT NEEDLE	70562	35904 - Metered-delivery hypodermic syringe
8697427708330	AYSET	2 PARTS 20ML SYRINGE WITHOUT NEEDLE	70568	35904 - Metered-delivery hypodermic syringe
8697427708569	AYSET	3 PARTS 2ML SYRINGE WITHOUT NEEDLE	70591	35904 - Metered-delivery hypodermic syringe
8697427708682	AYSET	3 PARTS 5ML SYRINGE WITHOUT NEEDLE	70604	35904 - Metered-delivery hypodermic syringe
8697427708743	AYSET	3 PARTS 10ML SYRINGE WITHOUT NEEDLE	70611	35904 - Metered-delivery hypodermic syringe
8697427708835	AYSET	3 PARTS 20ML SYRINGE WITHOUT NEEDLE	70625	35904 - Metered-delivery hypodermic syringe
8697427708927	AYSET	3 PARTS 50ML FEEDING, CATHETER TIP SYRINGE	70634	35904 - Metered-delivery hypodermic syringe
8697427709603	AYSET	3 PARTS 50ML LUER LOCK SYRINGE WITHOUT NEEDLE	70710	35904 - Metered-delivery hypodermic syringe
8697427709672	AYSET	2 PARTS 2ML SYRINGE WITHOUT NEEDLE	70717	35904 - Metered-delivery hypodermic syringe
8697427708217	AYSET	2 PARTS 5ML SYRINGE WITHOUT NEEDLE	81072	35904 - Metered-delivery hypodermic syringe
8697427708682	AYSET	3 PARTS 5ML SYRINGE WITHOUT NEEDLE	81079	35904 - Metered-delivery hypodermic syringe
8680738803214	AYSET	3 PARTS 2ML LUER LOCK SYRINGE WITHOUT NEEDLE	81347	35904 - Metered-delivery hypodermic syringe
8680738803245	AYSET	3 PARTS 2,5ML SYRINGE WITHOUT NEEDLE	81350	35904 - Metered-delivery hypodermic syringe
8680738803276	AYSET	3 PARTS 2,5ML LUER LOCK SYRINGE WITHOUT NEEDLE	81353	35904 - Metered-delivery hypodermic syringe
8680738803344	AYSET	3 PARTS 5ML LUER LOCK SYRINGE WITHOUT NEEDLE	81360	35904 - Metered-delivery hypodermic syringe
8680738803351	AYSET	3 PARTS 10ML LUER LOCK SYRINGE WITHOUT NEEDLE	81361	35904 - Metered-delivery hypodermic syringe
8680738803368	AYSET	3 PARTS 20ML LUER LOCK SYRINGE WITHOUT NEEDLE	81362	35904 - Metered-delivery hypodermic syringe



Nr.	Numărul de catalog (referință)*	Denumire generică (denumirea dispozitivului)	Denumire comercială (brand)*	Modelul	Cod GMDN*
1		Seringă		50ml fără ac	35904
2		Seringă		50ml cu ac	35904

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