

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 **TOTAL ITH. IHR. VE PAZ. LTD. ŞTI, Turcia**:

- Cîmp chirurgical pentru ochi cu apertura si punga pentru colectare, INTERSET

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 **28.09.2023**

Semnătura \_\_\_\_\_



**Tablelul 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	

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. 352<sup>1</sup>, Codul Penal al Republicii Moldova cu privire la falsul în declarații, că documentele și datele furnizate pentru notificarea dispozitivelor medicale ale producătorului producătorului **TOTAL ITH. IHR. VE PAZ. LTD. ȘTI, Turcia:**

- Cîmp chirurgical pentru ochi cu apertura si punga pentru colectare, INTERSET

**Sunt autentice și corespund realității.**

*Numele, prenumele și funcția:*

*RA-Manager – Sandu Irina*

Semnătura



Data **28.09.2023**

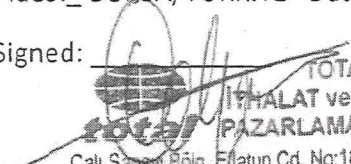
We, TOTAL İTHALAT VE İHRACAT PAZARLAMA LTD. ŞTİ.

based in Çalı Sanayii Bölgesi Eflatun cad. No:18 Nilüfer / BURSA, assign Dita Estfarm LLC, based in No.23 Burebista street, Chisinau MD -2032, Republic of Moldova, as **authorized representative** in correspondence with the conditions of Regulation (EU) 93/42.

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: \_ BURSA/TURKIYE Date: 01.08.2022

Signed:

  
TOTAL  
İTHALAT ve İHRACAT  
PAZARLAMA LTD. ŞTİ.  
Çalı Sanayii Böl. Eflatun Cd. No:18 Çalı / BURSA  
Tel: (0.224) 482 40 36 Fax: 482 40 37  
Ertuğrulgazi V.D.: 858 004 4311





DISPOSABLE SURGICAL GOWNS AND DRAPES



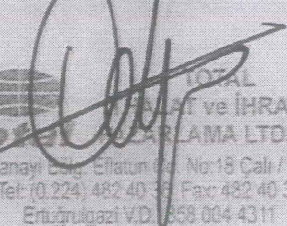
İTHALAT - İHRACAT LTD.ŞTİ.

TOTAL İTHALAT VE İHRACAT PAZARLAMA LTD. ŞTİ produces disposable surgical drapes and gowns under the INTERSET brand. At the same time, INTERSET MEDICAL SANAYİ TİCARET LTD ŞTİ's 60% partner and export operations are carried out by INTERSET MEDICAL SANAYİ TİCARET LTD ŞTİ.

Date  
31.12.2021

Sign and Stamp



  
TOTAL  
İTHALAT ve İHRACAT  
PAZARLAMA LTD. ŞTİ.  
Çalı Sanayi Bölge Eflatun Cad. No:18 Çalı / BURSA  
Tel: (+90 224) 482 40 36 Fax: 482 40 37  
Erişirgazi V.D. 058 004 4311



ÇALI SANAYİ BÖLGESİ EFLATUN CADDE NO:18 BURSA /TÜRKİYE  
TEL : +90 224 482 40 36 FAKS : +90 224 482 40 37  
info@interset.com.tr / www.interset.com.tr  
info@agnigel.com.tr / www.agnigel.com.tr



INTERSET ve AGNIGEL TOTAL İTH. İHR. LTD'nin tescilli markası olup Bursa tesislerinde üretilmektedir.  
INTERSET and AGNIGEL are the registered trademark of Total export-import co. and produced in Bursa.



# EC CERTIFICATE

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

Company Name : Total İth. İhr. ve Paz. Ltd. Şti.

Company Address : Çalı Sanayi Bölgesi, Eflatun Cadde No: 18 Çalı BURSA / TURKEY

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

Product : Sterile Disposable Drapes, Gowns and Sets - Class Is

GMDN : 47783, 46697, 42559, 39230, 43970, 37450, 35374, 13735, 35778

Certificate Number : M.2021.106.14349

Report Number : MD.4159.İB

Initial Assessment Date : 12.01.2021

Registration Date : 09.03.2021

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).



Address: Mıtlukent 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@udemlifd.com.tr](mailto:info@udemlifd.com.tr) [www.udem.com.tr](http://www.udem.com.tr)



## DECLARATION OF CONFORMITY

Doküman No	TD.01-B.4.2.B
Yayın Tarihi	09.03.2021
Rev. Tarihi	28.04.2021
Rev. No	01
Sayfa No	1 / 2

## DECLARATION OF CONFORMITY

Manufacturer Name : TOTAL İth. İhr. ve Paz. Ltd. Şti.

Adress : Çalı Sanayi Bölgesi, Karaali Mh. Eflatun Cadde No:18 Nilüfer BURSA/ TURKEY

Phone number : +90 224 482 40 36

Fax : +90 224 482 40 37

Website: : [info@interset.com.tr](mailto:info@interset.com.tr)

Product Name : STERILE SINGLE USE SURGICAL DRAPES

Product Models See Annex I

Product Class :93/42/EEC Medical Device Directive Annex IX, Rule 1 Class Is

GMDN Code and GMDN Code Explanation:



STERILE SINGLE USE SURGICAL DRAPES	47783 - A sterile, noninvasive flat sheet designed to cover a portion of a patient's anatomy during a surgical procedure to isolate a specific anatomical site (e.g., site of surgical incision) from potential contamination (e.g., microbial, substance). The device may also be used to protect a patient from heat/flame during a surgical procedure, however it is not designed with specific heat-reflective or laser resistant materials. This is a single-use device.
Eye Drape (With / Without Pouch)	46697- Ophthalmic Surgical Drape A protective covering made of natural or synthetic materials, or both, designed to promote a clean and dry sterile field about the eye during ophthalmic surgery or refractive and general ophthalmic office procedures. The device may be used to cover the eyebrow, retract lashes or eyelids, completely occlude the eyelid, or completely cover the eye. The device is typically secured directly to the skin with a pressure-sensitive adhesive, and is typically supplied sterile. This is a single-use device

Conformity Assessment Route : 93/42/EEC Medical Device Directive Annex V Production Quality Assurance System

Sterile Product Life: 3 year

We hereby declare that the above mentioned products meet the provisions of the Council Directive 93/42/EEC for medical devices. All supporting documentation is retained under the premises of the manufacturer.



## DECLARATION OF CONFORMITY

Doküman No	TD.01-B.4.2.B
Yayın Tarihi	09.03.2021
Rev. Tarihi	28.04.2021
Rev. No	01
Sayfa No	2 / 2

### Standards Applied :

EN ISO 13485:2016, 93/42/EEC, 2007/47/EC, EN ISO 15223-1:2016, EN 1041:2015, EN ISO 14971:2019, EN ISO 10993-1:2009, EN ISO 10993-5:2009, EN ISO 10993-7:2008, EN ISO 10993-10:2013, EN ISO 10993-12:2012, EN ISO 11737-1:2018, EN ISO 11737-2:2010, EN ISO 11607-1:2017, EN ISO 11607-2:2017, EN 62366:2015, ISO 11135:2014, EN ISO 11138-2:2017, EN ISO 11140-1:2009, EN 556-1:2001, EN 13795-1:2019, EN ISO 811:2018, EN 29073-3:1992, EN ISO 9073-10:2004, ISO 13938-1:2019, ISO 22610:2018

**Notified Body** : UDEM Uluslararası Belgelendirme Denetim Eğitim Merkezi San. ve Tic. A.Ş.  
Mutlukent Mahallesi 2073 Sokak (Eski 93 Sokak) No:10  
Ümitköy-ÇANKAYA/ANKARA, NB:2292

EC Certificate Number: M.2021.106.14349

Start Of CE Marking Date: 09.03.2021

CE Marking End Date : 27.05.2024

Place of Issue Date : Bursa, 27.09.2023



STERILE SINGLE USE SURGICAL DRAPES

**TUNCA BİLGİÇ**  
(General Manager)  
TOTAL  
İTHALAT ve İHRACAT  
PAZARLAMA LTD.ŞTİ.  
Çalı Sanayi Bölge, Eftalya Cd. No:18 Çalı /BURSA  
Tel: (0.224) 482 40 36 Fax: 482 40 37  
Erişim: 858 004 4311

Product Codes	Product Name	Dimensions (Min. Max.)	GMDN Code
INT-7000-013	SMS LAMİNATED OPERATIVE DRAPE	80-200cm	46697
INT-7000-013S	SMS OPETAVİTE DRAPE	80-200cm	46697
INT-7000-014	SMS LAMİNATED OPERATIVE DRAPE	80-200cm	46697
INT-7000-014S	SMS OPETAVİTE DRAPE	80-200cm	46697

Nr.	Numărul de catalog (referință)*	Denumire generică (denumirea dispozitivului)	Denumire comercială (brand)*	Modelul	Cod GMDN*
1		Cîmp chirurgical pentru ochi	INTERSET	cu apertura si punga pentru colectare	46697

