

**DEPARTMENT OF HEALTH AND HUMAN SERVICES  
Food and Drug Administration  
Center for Devices and Radiological Health  
10903 New Hampshire Ave., WO66 Room 2621  
Silver Spring, Maryland 20993-0002**

May 27, 2020

Name of Official Correspondent                      FATMA UNAKITAN CEVIK  
Address of Official Correspondent              CILEHANE YOLU CADESİ CAMLICA EVLERİ SİTESİ  
ISTANBUL, ISTANBUL 34696  
TURKEY  
[FUNAKITAN@TBI.COM.TR](mailto:FUNAKITAN@TBI.COM.TR)  
Owner Operator Number                      10074374

Dear Sir or Madam,

We have received your registration and listing information for the following medical device establishment

Establishment Name                      SEBAT TARIM URUNLERİ PAZARLAMA VE TİC A.Ş  
Establishment Address                      CILEHANE YOLU CADESİ CAMLICA EVLERİ SİTESİ  
ISTANBUL, ISTANBUL 34696  
TURKEY

The information submitted has been processed and entered into the FDA Registration and Device Listing Database. Your device establishment is now considered registered. You will be notified of your official registration number within 90 days.

Once you receive a registration number, you are required to re-register on an annual basis from October through December. Failure to re-register every year will invalidate your registration and result in your device establishment and listing information being removed from the FDA Medical Device Registration and Listing Web site.

For inquiries about the status of your registration or assignment of your registration

## DEVICE REGISTRATION AND LISTING INFORMATION

Please review your registration.

Registration Date: May 27, 2020  
Registration Status: Active, Waiting for Registration  
Number Assignment

Section 01	Type of Registration
Activities	MANUFACTURER
Registration Number	Not Yet Assigned

Section 02	Facility Name / Address Information
Name	SEBAT TARIM URUNLERI PAZARLAMA VE TIC A.S
Address	CILEHANE YOLU CADDESI CAMLICA EVLERI SITESI ISTANBUL, ISTANBUL 34696 TURKEY

Section 03	Owner/Operator Information
Owner/Operator Number	10074374
Contact Name	FATMA UNAKITAN CEVIK
Company	SEBAT TARIM URUNLERI PAZARLAMA VE TIC A.S
Address	CILEHANE YOLU CADDESI CAMLICA EVLERI SITESI ISTANBUL, ISTANBUL 34696 TURKEY
Phone Number	(90) (533) 2312601
Fax Number	
Email Address	funakitan@tbi.com.tr

Section 04	Official Correspondent Information
OC Contact Name	FATMA UNAKITAN CEVIK
OC Business Name	SEBAT TARIM URUNLERI PAZARLAMA VE TIC A.S
Address	CILEHANE YOLU CADDESI CAMLICA EVLERI SITESI ISTANBUL, ISTANBUL 34696 TURKEY
Phone Number	(90) (533) 2312601
Fax Number	
Email Address	funakitan@tbi.com.tr

Section 05	Trade Names
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Section 06	United States Agent
Contact Name	TOLGA HOROZ
Business Name	
Address	1860 6TH AVENUE SAN DIEGO, CALIFORNIA 92101 UNITED STATES
Phone Number	(619) 531-0100
Fax Number	
Email Address	tolga@awccco.com

Section 07	Listings
Listing #1	
Listing Number	D404983
Listing Status	ACTIVE
Created Date	May 27, 2020 6:50:09 AM ET
Submission Number	
Proprietary Names	SurgiMask
Listing #2	
Listing Number	D404982
Listing Status	ACTIVE
Created Date	May 27, 2020 6:50:09 AM ET
Submission Number	
Proprietary Names	SurgiGown

Owner Operator Number

10074374

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Establishment Name

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Establishment Address

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