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✓ Facility

✓ Products Listing

Registration Confirmation

Facility: AGAMED HEALTH LLC, Los Angeles, California, UNITED STATES

You have successfully entered your facility registration and device listing information. You should print a copy of this page for your records. Listing numbers appear below for the products manufactured, developed, or processed at this facility.

As a manufacturer, specification developer, or single-use device reprocessor, you are required to pay an annual fee for medical device facility registration.

You will receive another e-mail providing you with your registration number in approximately 30 to 90 days. Until your registration number is assigned, reference your Owner/Operator number in any correspondence with the Center for Devices and Radiological Health.

Your registration will be valid through Dec 31, 2022. An e-mail will be sent to the Owner/Operator and the Official Correspondent 90 days before the facility is required to re-register for Fiscal Year 2022 with instructions on how and when to re-register.

Note: Registering your device facility and listing your devices does not, in any way, constitute FDA approval of your facility or your devices.

Should you have any questions, please send an e-mail to reglist@cdrh.fda.gov (<mailto:reglist@cdrh.fda.gov>).

The Owner/Operator Number for this Registration is: 10085211

Facility Information

Registration Number:

Initial Importer:

Y

Facility Name:

AGAMED HEALTH LLC

Legal Name:

Address:

633 West 5th Street Suit 2883B
Los Angeles, California, 90071, UNITED STATES

DUNS Number:

036829783

Foreign Trade Zone:

N

Facility URL:

Other Business Trade Name(s):

Establishment located on a campus:

Owner/Operator Information

Owner/Operator Number:
10085211

Contact Name:
ECE AGAOGLU POLAT

Company:
AGAMED HEALTH LLC

Address: 633 West 5th Street Suit 2883B
Los Angeles, CALIFORNIA, 90071, UNITED STATES

Telephone:
1 - 858 - 2148362

Fax:
-

E-mail: ece@agamedhealth.com

DUNS Number:
036829783

Official Correspondent Information

Contact Name:
ECE AGAOGLU POLAT

Company:
AGAMED HEALTH LLC

Address: 633 West 5th Street Suit 2883B
Los Angeles, CALIFORNIA, 90071, UNITED STATES

Telephone:
1 - 858 - 2148362

Fax:
-

E-mail: ece@agamedhealth.com

DUNS Number:
036829783

No Listings Required.

Imported Products and Manufacturers

Manufacturer(s) Name	Address	Product Code	Device Name	Premarket Submission Number
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AGA OGLU TIBBI SAGLIK TEKSTIL SANAYI VE TICARET ANONIM SIRKETI	ORGANIZE SANAYI BOLGESI, N:219 TEKSTIL OSB MAHALLESİ 104 CADDE, Merkez, Usak, 64000, TURKEY	KGX	Tape and bandage, adhesive	
AGA OGLU TIBBI SAGLIK TEKSTIL SANAYI VE TICARET ANONIM SIRKETI	ORGANIZE SANAYI BOLGESI, N:219 TEKSTIL OSB MAHALLESİ 104 CADDE, Merkez, Usak, 64000, TURKEY	FQM	BANDAGE, ELASTIC	
AGA OGLU TIBBI SAGLIK TEKSTIL SANAYI VE TICARET ANONIM SIRKETI	ORGANIZE SANAYI BOLGESI, N:219 TEKSTIL OSB MAHALLESİ 104 CADDE, Merkez, Usak, 64000, TURKEY	NAB	Gauze / sponge, nonresorbable for external use	
AGA OGLU TIBBI SAGLIK TEKSTIL SANAYI VE TICARET ANONIM SIRKETI	ORGANIZE SANAYI BOLGESI, N:219 TEKSTIL OSB MAHALLESİ 104 CADDE, Merkez, Usak, 64000, TURKEY	ILG	STOCKING, ELASTIC	
AGA OGLU TIBBI SAGLIK TEKSTIL SANAYI VE TICARET ANONIM SIRKETI	ORGANIZE SANAYI BOLGESI, N:219 TEKSTIL OSB MAHALLESİ 104 CADDE, Merkez, Usak, 64000, TURKEY	HMP	PAD, EYE	

Date of Initial Registration: Thu May 19 19:20:11 EDT 2022