

Registration Successful

Facility: TWM- TSADIK WEISER MEDICAL LTD, Otniel, Southern, ISRAEL

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, 2025. 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 2026 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.

The Owner/Operator Number for this Registration is: 10092857

Facility Information

Registration Number:

N

Initial Importer:

TWM- TSADIK WEISER MEDICAL LTD

Facility Name:

Legal Name:

Address:

149 Revava street,,
Otniel, Southern, 9040700, ISRAEL

DUNS Number:

N

Foreign Trade Zone:

Facility URL:

<https://t-w-medical.com/en/>

Other Business Trade Name(s):

Establishment located on a campus:

Owner/Operator Information

Owner/Operator Number:

10092857

Contact Name:

Yaakov Tsadik

Company:

TWM- TSADIK WEISER MEDICAL LTD

Address:

149 Revava street,
Otniel, SOUTHERN, 9040700, ISRAEL

Telephone:

972 - 54 - 7449946

Fax:

-

E-mail:

ran@sync.co.il

DUNS Number:

Official Correspondent Information

Contact Name:

Ran Amos

Company:

TWM- Tsadik Weiser Medical Ltd

Address:

Prof. Yehudit Birk street 1A/25
Rehovot, CENTRAL, 7608662, ISRAEL

Telephone:

972 - 52 - 6736436

Fax:

-

E-mail:

ran@sync.co.il

DUNS Number:

United States Agent Information

Contact First Name

Sung

Contact Last Name

Kwon

Contact Title:

Ms

Business Name:

NEXGEN HEALTH GROUP INC.

Address:

13925 City Center Dr Ste 200
Chino Hills, California, 91709, UNITED STATES

Phone:

909 - 2298249

Fax:

909 -4933276

DUNS Number:

E-mail:

ran@sync.co.il

Device Listings

Listing Number	Premarket Submission Number	Premarket Submission Type	Product Code(s)	Device Name(s)	Activities	Importers
D561995		510(k) exempt	GAX	TOURNIQUET, NONPNEUMATIC	Manufacturer	NEXGEN HEALTH GROUP INC.