

✓ Facility

✓ Products Listing

Annual Registration Successful

Facility: Calze G.T. Srl, CASALOLDO, Mantova, ITALY

You have successfully updated your registration and listing information for 2023.

Your registration will be valid through Dec 31, 2023.

Be sure to print this page for your records.

The next registration renewal period is October 1 - December 31, 2023.

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

You may contact the FDA with any questions at reglist@cdrh.fda.gov.

The Owner/Operator Number for this Registration is: 10023307.

Facility Information

Registration Number:	3006801236
Initial Importer:	N
Facility Name:	Calze G.T. Srl
Legal Name:	
Address:	Via Castel Goffredo 31/33 CASALOLDO, Mantova, 46040, ITALY
DUNS Number:	
Foreign Trade Zone:	N
Facility URL:	
Other Business Trade Name(s):	

Establishment located on a campus:

Owner/Operator Information

Owner/Operator Number: 10023307
Contact Name: Cristiano Gorgaini
Company: CALZE G.T. SRL
Address: Via Castel Goffredo 31/33
CASALOLDO, MANTOVA, 46040, ITALY
Telephone: 39 - 0376 - 780686
Fax: -
E-mail: cristiano@relaxsan.it
DUNS Number:

Official Correspondent Information

Contact Name: Cristiano Gorgaini
Company: CALZE G.T. SRL
Address: Via Castel Goffredo 31/33
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Telephone: 39 - 0376 - 780686
Fax: -
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DUNS Number:

United States Agent Information

Contact First Name: Cristiano
Contact Last Name: Gorgaini
Contact Title: Mr
Business Name: GT NORTH AMERICA CORP.
Address: 18 Bridge Street Unit 2A
Brooklyn, New York, 11201, UNITED STATES
Phone: 718 - 5225575
Fax:
DUNS Number:
E-mail: cristiano@relaxsan.it

Device Listings

Listing Number	Premarket Submission Number	Premarket Submission Type	Product Code(s)	Device Name(s)	Activities	Importers
D427779		510(k) exempt	IQF	ORTHOISIS, CERVICAL-THORACIC, RIGID	Manufacturer	GT NORTH AMERICA CORP.
D454062		510(k) exempt	DWL	Stocking, medical support (to prevent pooling of blood in legs)	Manufacturer	GT NORTH AMERICA CORP.
D454063		510(k) exempt	IQE	ORTHOISIS, LUMBAR	Manufacturer	GT NORTH AMERICA CORP.
D011634		510(k) exempt	FQL	STOCKING, MEDICAL SUPPORT (FOR GENERAL MEDICAL PURPOSES)	Manufacturer	GT NORTH AMERICA CORP.
D454064		510(k) exempt	ITQ	JOINT, KNEE, EXTERNAL BRACE	Manufacturer	GT NORTH AMERICA CORP.
D454065		510(k) exempt	IOY	SUPPORT, ARM	Manufacturer	GT NORTH AMERICA CORP.

Date of Initial Registration: 2007-11-15 15:57:18.0