

ROYAL SENSE LIMITED

Registered Office: Plot No. 57, First Floor, Phase-II, Badli Industrial Estate, Badli (North West Delhi), Delhi-110042

CIN: L21006DL2023PLC412051 Email: compliance@royalsense.in Website: www.royalsense.in | Contact No.: +91-9205843102

Date: 16-11-2024

To

The Manager – Listing Department BSE Limited P. J. Towers, Dalal Street, Mumbai – 400 001

<u>Subject: Intimation under Regulation 30 of SEBI (LODR) Regulations, 2015 - Application</u> submission for License/U.S. FDA Certification

Dear Sir/Madam,

Pursuant to Regulation 30 of the SEBI (Listing Obligations and Disclosure Requirements) Regulations, 2015, we wish to inform you that the Company has applied for the License/U.S. FDA Certification in compliance with the requirements of the U.S. Food and Drug Administration (FDA) on 15th November, 2024.

The license/U.S. FDA Certification has been applied for the following products are as follows:

S.No	Device Name	Activities
1	Joint Knee, External Brace	Manufacturer,
		Repackager/Relabeler
2	Joint Ankle, External Brace	Manufacturer,
		Repackager/Relabeler
3	Binder, Abdominal	Manufacturer,
		Repackager/Relabeler

This certification is seeking for the expansion of business and ensuring the facility meets the necessary regulatory standards and quality assurance requirements and the Company is actively engaging with the U.S. FDA authorities to ensure all requirements are satisfactorily met.

We shall keep the Stock Exchange(s) and stakeholders informed about further developments in this matter as and when applicable.

We request you to take the above information on record.



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Thanking You,

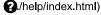
For Royal Sense Limited

Rishabh Arora Managing Director DIN:09745543

Enclosure: Application Acknowledgement

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DRLM Home (mainMenu.htm) > Register a New Medical Device Facility

✓ Facility

✓ Products Listing

Registration Confirmation

Facility: ROYAL SENSE LIMITED, DELHI, Delhi, INDIA

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 2025 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: 10091909

Facility Information

Registration Number:

Initial Importer:

Facility Name: ROYAL SENSE LIMITED

Legal Name:

Address: C-7, PHASE -III, BADLI INDUSTRIAL AREA

DELHI, Delhi, 110042, INDIA

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DUNS Number: 957052153

Foreign Trade Zone: N

Facility URL: http://www.royalsense.in

Other Business Trade Name(s):

Establishment located on a

campus:

Owner/Operator Information

Owner/Operator Number: 10091909

Contact Name: RISHABH ARORA
Company: ROYAL SENSE LIMITED

Address: C-7, PHASE -III, BADLI INDUSTRIAL AREA

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DELHI, DELHI, 110042, INDIA

Telephone: 91 - 011 - 9717273 - 604

Fax:

E-mail: gaurav@royalsense.in

DUNS Number: 957052153

Official Correspondent Information

Contact Name: RISHABH ARORA

Company: ROYAL SENSE LIMITED

Address: C-7, PHASE -III, BADLI INDUSTRIAL AREA

DELHI, DELHI, 110042, INDIA

Telephone: 91 - 011 - 9717273 - 604

Fax:

E-mail: gaurav@royalsense.in

DUNS Number: 957052153

United States Agent Information

Contact First Name Geetu
Contact Last Name Arora
Contact Title: Ms

Business Name: TTG INNOVATIONS INC Address: 8 The Green, Ste A, Dover

Dover, Delaware, 19901, UNITED STATES

Phone: 302 - 5051821

Fax:

DUNS Number:

E-mail: geetu@ttginnovations.com

Device Listings

Listing Number	Premarket Submission Number	Premarket Submission Type	Product Code(s)	Device Name(s)	Activities	Importers
D549468		510(k) exempt	ITQ	JOINT, KNEE, EXTERNAL BRACE	Manufacturer Repackager/Relabeler	
D549470		510(k) exempt	ITW	JOINT, ANKLE, EXTERNAL BRACE	Manufacturer Repackager/Relabeler	
D549471		510(k) exempt	FSD	BINDER, ABDOMINAL	Manufacturer Repackager/Relabeler	

Date of Initial Registration: Fri Nov 15 02:19:41 EST 2024