

प्रेषक,

औषधि अनुज्ञापन एवं नियंत्रण प्राधिकारी,  
कार्यालय आयुक्त,  
खाद्य सुरक्षा एवं औषधि प्रशासन, उ०प्र०,  
सेक्टर-सी, अलीगंज, लखनऊ।

सेवा में,

M/s Shree Jee Industries,  
Near Mandi Samittee, Moradabad Road, Man Nagar Kanth,  
Uttar Pradesh (India)

सं०: MFG/MD/2019/12696/918/

लखनऊ दिनांक 18.03.2020

विषय : प्रपत्र-MD-5 पर मेडिकल डिवाइस निर्माण अनुमति प्रदान किये जाने के सम्बन्ध में।

महोदय,

उपर्युक्त विषयक आपके ऑन-लाईन आवेदन पत्र पर विचारोपरान्त फार्म एमडी-5 पर मेडिकल डिवाइस निर्माण हेतु नवीन लाइसेंस संख्या-MFG/MD/2020/000074, दिनांक 18.03.2020 मेडिकल डिवाइस रूल्स, 2017 में निहित प्राविधानों एवं औषधि एवं प्रसाधन सामग्री अधिनियम, 1940 के अधीन स्वीकृत कर प्रेषित किया जा रहा है। अनुज्ञापी द्वारा कम से कम प्रारम्भिक तीन व्यवसायिक बैच का स्टेबिलिटी डेटा उपलब्ध कराया जायेगा।

संलग्नक-उपरोक्तानुसार।

भवदीय

(ए०के० जैन)

औषधि अनुज्ञापन एवं नियंत्रण प्राधिकारी,  
उत्तर प्रदेश।

सं०: MFG/MD/2019/12696/918/

तद्दिनांक

प्रतिलिपि निम्नलिखित को सूचनार्थ एवं आवश्यक कार्यवाही हेतु प्रेषित-

- (1) सहायक आयुक्त (औषधि), खाद्य सुरक्षा एवं औषधि प्रशासन, कार्यालय मण्डलायुक्त, मुरादाबाद मण्डल।
- (2) औषधि निरीक्षक, खाद्य सुरक्षा एवं औषधि प्रशासन, कार्यालय जिलाधिकारी, मुरादाबाद।

(ए०के० जैन)

औषधि अनुज्ञापन एवं नियंत्रण प्राधिकारी,  
उत्तर प्रदेश।



सत्यमेव जयते

## FORM MD-5

[See sub-rule (4) of rule 20 and sub-rule (6) of rule 20]

Licence to Manufacture for Sale or for Distribution of Class A or Class B medical device

Licence Number: MFG/MD/2020/000074

1. M/s Shree Jee Industries, Near Mandi Samittee, Moradabad Road, Man NagarKanth, --, Uttar Pradesh (India) - 244501 Telephone No.: 9412411484 FAX: 9412411484 has been licenced to manufacture for sale or for distribution the below listed medical device(s) at the premises situated at M/s SHREE JEE INDUSTRIES, MANDI SAMITTEE, KANTH, MORADABAD , Moradabad, Uttar Pradesh (India) - 244501 Telephone No.: 9412411484 FAX: 591-2220061

2. Details of medical device(s) [Annexed]

3. This licence is subject to the provisions of the Medical Devices Rules, 2017 and conditions prescribed therein.

### ANNEXURE

S.No.	Details Of Device(s)
1	Generic Name:COTTON BANDAGE CLOTH Model No.:NIL Intended Use:To support the Draping. Class of medical device:Class B Material of construction:Cotton Yarn Dimension(if any):90 cm X 20 Meter, 100 cm X 20 Meter, 100 cm X 18 Meter, 90 cm X 18 Meter, 120 cm X 20 Meter, 100 cm X 16 Meter, 90 cm X 16 Meter Shelflife:3 Years Sterile or Non sterile:Non-Sterilized Brand Name(if registered under the Trade Marks Act, 1999):NIL
2	Generic Name:ABSORBENT GAUZE CLOTH Model No.:NIL Intended Use:for clean the wound Class of medical device:Class B Material of construction:Cotton Yarn Dimension(if any):60 cm x 16 Meter, 60 cm x 18 Meter, 60 cm x 20 Meter, 90 cm x 16 Meter, 90 cm x 18 Meter, 90 cm x 20 Meter, 90 cm x 100 Meter, 90 cm x 90 Meter, 100 cm x 18 Meter, 100 cm x 20 Meter, 90 cm x 1 Meter, 90 cm x 5 Meter, 100 cm x 6 Meter, 100 cm x 5 Meter, 90 cm x 6 Meter, 90 cm x 12 Meter Shelflife:3 Years Sterile or Non sterile:Both Brand Name(if registered under the Trade Marks Act, 1999):NIL

3	<p>Generic Name:CREPE BANDAGE</p> <p>Model No.:NIL</p> <p>Intended Use:for the Reduces swelling, Secures wound dressing, Supports strains and sprains</p> <p>Class of medical device:Class B</p> <p>Material of construction:Cotton yarn, viscose yarn</p> <p>Dimension(if any):Stretch Length= 6 cm x 4 Meter, 6 cm x 3 Meter, 6 cm x 4.5 Meter, 6 cm x 1 Meter, 8 cm x 4 Meter, 8 cm x 3 Meter, 8 cm x 4.5 Meter, 8 cm x 1 Meter, 10 cm x 4 Meter, 10 cm x 3 Meter, 10 cm x 4.5 Meter, 10 cm x 1 Meter, 15 cm x 4 Meter, 15 cm x 3 Meter, 15 cm x 4.5 Meter, 15 cm x 1 Meter.</p> <p>Shelflife:3 Years</p> <p>Sterile or Non sterile:Non-Sterilized</p> <p>Brand Name(if registered under the Trade Marks Act, 1999):NIL</p>
4	<p>Generic Name:OPEN WOVE BANDAGE</p> <p>Model No.:NIL</p> <p>Intended Use:it is used to cover the wounds to prevent it from dust and bacteria</p> <p>Class of medical device:Class B</p> <p>Material of construction:Cotton yarn</p> <p>Dimension(if any):5 cm X 2 Meter, 5 cm X 2.5 Meter, 5 cm X 2.7 Meter, 5 cm X 3 Meter, 5 cm X 3.3 Meter, 5 cm X 3.6 Meter, 5 cm X 4 Meter, 5 cm X 4.5 Meter, 5 cm X 5 Meter, 5 cm X 9 Meter, 5 cm X 10 Meter, 7.5 cm X 2 Meter, 7.5 cm X 2.5 Meter, 7.5 cm X 2.7 Meter, 7.5 cm X 3 Meter, 7.5 cm X 3.3 Meter, 7.5 cm X 3.6 Meter, 7.5 cm X 4 Meter, 7.5 cm X 4.5 Meter, 7.5 cm X 5 Meter, 7.5 cm X 6 Meter, 7.5 cm X 9 Meter, 7.5 cm X 10 Meter, 10 cm X 2 Meter, 10 cm X 2.5 Meter, 10 cm X 2.7 Meter, 10 cm X 3 Meter, 10 cm X 3.3 Meter, 10 cm X 3.6 Meter, 10 cm X 4 Meter, 10 cm X 4.5 Meter, 10 cm X 5 Meter, 10 cm X 6 Meter, 10 cm X 9 Meter, 10 cm X 10 Meter, 15 cm X 2 Meter, 15 cm X 2.5 Meter, 15 cm X 2.7 Meter, 15 cm X 3 Meter, 15 cm X 3.3 Meter, 15 cm X 3.6 Meter, 15 cm X 4 Meter, 15 cm X 4.5 Meter, 15 cm X 5 Meter, 15 cm X 6 Meter, 15 cm X 9 Meter, 15 cm X 10 Meter, 12 cm X 2 Meter, 12 cm X 2.5 Meter, 12 cm X 2.7 Meter, 12 cm X 3 Meter, 12 cm X 3.3 Meter, 12 cm X 3.6 Meter, 12 cm X 4 Meter, 12 cm X 4.5 Meter, 12 cm X 5 Meter, 12 cm X 6 Meter, 12 cm X 9 Meter, 12 cm X 10 Meter, 9 cm X 2 Meter, 9 cm X 2.5 Meter, 9 cm X 2.7 Meter, 9 cm X 3 Meter, 9 cm X 3.3 Meter, 9 cm X 3.6 Meter, 9 cm X 4 Meter, 9 cm X 4.5 Meter, 9 cm X 5 Meter, 9 cm X 6 Meter, 9 cm X 9 Meter, 9 cm X 10 Meter</p> <p>Shelflife:3 Years</p> <p>Sterile or Non sterile:Non-Sterilized</p> <p>Brand Name(if registered under the Trade Marks Act, 1999):NIL</p>
5	<p>Generic Name:GAUZE SWAB</p> <p>Model No.:NIL</p> <p>Intended Use:for wound dressing, padding, protection, blood spill, applying antiseptic</p> <p>Class of medical device:Class B</p> <p>Material of construction:Cotton Yarn</p> <p>Dimension(if any):5CM X 5CM X8 PLY, 5CM X 5CM X 12 PLY, 5CM X 5CM X 16 PLY, 7.5CM X 7.5 CM X8 PLY, 7.5CM X 7.5 CM X12 PLY, 7.5CM X 7.5 CM X 16 PLY, 10 CM X 10 CM X 8 PLY, 10 CM X 10 CM X 12 PLY, 10 CM X 10 CM X 16 PLY</p> <p>Shelflife:3 Years</p> <p>Sterile or Non sterile:Both</p> <p>Brand Name(if registered under the Trade Marks Act, 1999):NIL</p>

6	<p>Generic Name:ABDOMINAL PAD  Model No.:NIL  Intended Use:FOR THE ABSORPTION OF DISCHARGES FROM ABDOMINAL WOUND  Class of medical device:Class B  Material of construction:Cotton Yarn  Dimension(if any):Non sterile-10 CM X 10 CM X 4/6/8/10/12/16 PLY 15CM X 15CM X 4/6/8/10/12/16/20/24/28 PLY 20 CM X 20 CM X 4/6/8/10/12/16/20/24/28 PLY 22.5CM X 22.5CM X 4/6/8/10/12/16/20/24/28 PLY 25CM X 25 CM X 4/6/8/10/12/16/20/24/28 PLY, 27CM X 27CM X 4/6/8/10/12/16/20/24/28 PLY 30CM X 30CM X 4/6/8/10/12/16/20/24/28 PLY 35CM X 35CM X 4/6/8/10/12/16/20/24/28 PLY 40CM X 40CM X 4/6/8/10/12/16/20/24/28 PLY 45CM X 45CM X 4/6/8/10/12/16/20/24/28 PLY 50CM X 50CM X 4/6/8/10/12/16/20/24/28 PLY 60CM X 60 CM X 4/6/8/10/12/16/20/24/28 PLY, Sterile– 10 CM X 10 CM X 4/6/8/10/12/16 PLY 15CM X 15CM X 4/6/8/10/12/16/20/24/28 PLY 20 CM X 20 CM X 4/6/8/10/12/16/20/24/28 PLY 22.5CM X 22.5CM X 4/6/8/10/12/16/20/24/28 PLY 25CM X 25 CM X 4/6/8/10/12/16/20/24/28 PLY 27CM X 27CM X 4/6/8/10/12/16/20/24/28 PLY 30CM X 30CM X 4/6/8/10/12/16/20/24/28 PLY 35CM X 35CM X 4/6/8/10/12/16/20/24/28 PLY 40CM X 40CM X 4/6/8/10/12/16/20/24/28 PLY 45CM X 45CM X 4/6/8/10/12/16/20/24/28 PLY 50CM X 50CM X 4/6/8/10/12/16/20/24/28 PLY 60CM X 60 CM X 4/6/8/10/12/16/20/24/28 PLY  Shelflife:3 Years  Sterile or Non sterile:Both  Brand Name(if registered under the Trade Marks Act, 1999):NIL</p>
7	<p>Generic Name:COMBINED DRESSING PAD  Model No.:NIL  Intended Use:These are ideal for handling heavy drainage, promoting healing and keeping the wound dry for optimal comfort and relief  Class of medical device:Class B  Material of construction:Cotton, non woven cloth  Dimension(if any):sterile-7.5 CM X 2/3/2.70/4/2.5/4.5/1.0 MTS 10 CM X 1/1.5/2/2.5/2.7/3/4/4.5/5 MTS 15 CM X 1/1.5/2/2.5/2.7/3/4/4.5/5 MTS 20CM X 1/1.5/2/2.5/2.7/3/4/4.5/5 MTS 15 CM X 25 CM , 25 CM X 25 CM , 45 CM X 30 CM 50 CM X 30 CM, 55 CM X 45 CM, 23 CM X 15 CM, 10 CM X 10 CM , 10 CM X 20 CM, 15 CM X 20 CM, 20 CM X 20 CM Sterile – 7.5 CM X 2/3/2.70/4/2.5/4.5/1.0 MTS 10 CM X 1/1.5/2/2.5/2.7/3/4/4.5/5 MTS 15 CM X 1/1.5/2/2.5/2.7/3/4/4.5/5 MTS 15 CM X 25 CM , 25 CM X 25 CM , 45 CM X 30 CM 50 CM X 30 CM, 55 CM X 45 CM, 23 CM X 15 CM 10 CM X 10 CM , 10 CM X 20 CM, 15 CM X 20 CM, 20 CM X 20 CM  Shelflife:3 Years  Sterile or Non sterile:Sterilized  Brand Name(if registered under the Trade Marks Act, 1999):NIL</p>

8	<p>Generic Name:ELASTIC ADHESIVE BANDAGE  Model No.:NIL  Intended Use:It is usually used to wrap soft tissue injuries to provide compression and support  Class of medical device:Class B  Material of construction:CREPE BANDAGE COATED WITH ZINC OXIDE AND NATURAL RUBBER PASTE  Dimension(if any):STRETCHED LENGTH= 6CM X 1 MTS 6 CM X 2/3 MTS 6CM X 4/6 MTS 8 CM X 1 MTS 8 CM X 2/3 MTS 8 CM X 2/3 MTS 10 CM X 1 MTS 10 CM X 2/3 MTS 10 CM X 4/6 MTS 15 CM X 1 MTS 15 CM X 2/3 MTS 15 CM X 4/6 MTS  Shelflife:3 Years  Sterile or Non sterile:Non-Sterilized  Brand Name(if registered under the Trade Marks Act, 1999):OSMOPLAST</p>
9	<p>Generic Name:IV CANNULA FIXATOR  Model No.:NIL  Intended Use:IV Cannula Fixator is helpful for fixing IV Cannula  Class of medical device:Class B  Material of construction:CREPE BANDAGE COATED WITH ZINC OXIDE AND NATURAL RUBBER PASTE  Dimension(if any):Non sterile and sterile= 5 CM X 8 CM, 5 CM X 7CM 6 CM X 8 CM  Shelflife:3 Years  Sterile or Non sterile:Both  Brand Name(if registered under the Trade Marks Act, 1999):NIL</p>
10	<p>Generic Name:Absorbent Cotton Gauze Ribbon  Model No.:NIL  Intended Use:used in dressings  Class of medical device:Class B  Material of construction:Cotton yarn  Dimension(if any):Non sterile and sterile= 1.25 CM X 1/2.5/3/5/4.5/90/100 MTS 2.5 CM X 1/2. 5/3/5/4.5/90/100 MTS 5 CM X 1/2.5/3/5/4.5/90/100 MTS  Shelflife:3 Years  Sterile or Non sterile:Both  Brand Name(if registered under the Trade Marks Act, 1999):NIL</p>
1 1	<p>Generic Name:Gamjee Roll  Model No.:NIL  Intended Use:for the Cleaning and drying Purpose  Class of medical device:Class B  Material of construction:Cotton, Absorben gauze cloth  Dimension(if any):7.5 CM X 2/3/2.70/4/2.5/4.5/1.0 MTS 10 CM X 1/1.5/2/2.5/2.7/3/4/4.5/5 MTS 15 CM X 1/1.5/2/2.5/2.7/3/4/4.5/5 MTS 20CM X 1/1.5/2/2.5/2.7/3/4/4.5/5 MTS 15 CM X 25 CM , 25 CM X 25 CM , 45 CM X 30 CM 50 CM X 30 CM, 55 CM X 45 CM, 23 CM X 15 CM, 10 CM X 10 CM , 10 CM X 20 CM, 15 CM X 20 CM, 20 CM X 20 CM  Shelflife:3 Years  Sterile or Non sterile:Both  Brand Name(if registered under the Trade Marks Act, 1999):NIL</p>

Place: Lucknow

Date:18-Mar-20

State Licensing Authority

Uttar Pradesh