



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/2024/000396

1. M/s SHRI LATHIKKA SURGICALS, 5-G 16/1, OTTATHIAMMAN KOVIL STREET, SANKARAPANDIYAPURAM, VIRUDHUNAGAR - 626102 TAMILNADU, INDIASANKARAPANDIYAPURAM, Virudhunagar, Tamil Nadu (India) - 626102 Telephone No.: 94862 86856 FAX: 94862 86856 has been licenced to manufacture for sale or for distribution the below listed medical device(s) at the premises situated at M/s SHRI LATHIKKA SURGICALS, 5-G 15/1 & 5-G 16/1, Ottathiamman Kovil Street, Sankarapandiapuram, Virudhunagar, Tamil Nadu (India) - 626102 Telephone No.: 8248764851 FAX: 8248764851

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: Absorbent Gauze IS 758 Model No.: NIL Intended Use: The Absorbent Gauze are used in general wound treatment, especially suitable in primary treatment of dirty, infected and highly exudates wounds Class of medical device: Class B Material of construction: Plain weave bleached cotton fabric as per the specification IS 758 Requirements Dimension(if any): Width 5cm to 250cm & Length 5cm to 100Meter X (4 to 32) Ply Shelflife: 3 Years Sterile or Non sterile: Non-Sterilized Brand Name(if registered under the Trade Marks Act, 1999): NIL
2	Generic Name: Bandage Cloth IS 863 Model No.: NIL Intended Use: The Bandage cloth is used for immobilize injured body parts, provide pressure to control internal or external bleeding, absorb drainage, and secure dressings Class of medical device: Class B Material of construction: Plain weave bleached cotton fabric as per the specification IS 863 Standard Requirements Dimension(if any): Width 5cm to 180cm, Length 10cm to 100 Meters Shelflife: 3 Years Sterile or Non sterile: Non-Sterilized Brand Name(if registered under the Trade Marks Act, 1999): NIL

3	Generic Name:Open Weave Bandage IS 16469 Model No.:NIL Intended Use:The Open Weave bandage used for immobilize injured body parts, provide pressure to control internal or external bleeding, absorb drainage, and secure dressings Class of medical device:Class B Material of construction:As per the specification IS 16469 Standard Requirements Dimension(if any):Width 5cm to 180cm, Length 1Meter to 100 Meters Shelflife:3 Years Sterile or Non sterile:Non-Sterilized Brand Name(if registered under the Trade Marks Act, 1999):NIL
4	Generic Name:Gauze Swabs BP 1988 Type 13 Light Model No.:NIL Intended Use:The Gauze Swabs are used for wound dressing, padding, protection, blood spill and to applying antiseptic Class of medical device:Class B Material of construction:As per the specification BP 1988 Standard Requirements Dimension(if any):Width 5cm to 20cm X Length 5cm to 20cm X (8 to 32) Ply Shelflife:3 Years Sterile or Non sterile:Non-Sterilized Brand Name(if registered under the Trade Marks Act, 1999):NIL
5	Generic Name:Gauze and Cotton Tissue BP 1988 Model No.:NIL Intended Use:The Gauze and Cotton Tissue are used for a large bleeding wound after initial bleeding has been controlled by direct pressure Class of medical device:Class B Material of construction:As per the specification BP 1988 Standard Requirements Dimension(if any):Width 5cm to 50cm X Length 5cm to 10Meters Shelflife:3 Years Sterile or Non sterile:Non-Sterilized Brand Name(if registered under the Trade Marks Act, 1999):NIL
6	Generic Name:X-Ray Detectable Absorbent Cotton Gauze IS 16950 Model No.:NIL Intended Use:The X-Ray Detectable Absorbent Cotton Gauze is used for wound dressing, padding, protection, blood spill and to applying antiseptic. X-Ray Detectable thread allows easy to detect if the dressing materials left in the body. Class of medical device:Class B Material of construction:Plain weave bleached, folded absorbent gauze and Monofilament or Multifilament Distinctly coloured X-Ray Detectable Yarn as per the specification IS 16950 Requirements. The X-Ray Detectable member consist of not less than 55 percent of barium sulphate giving a comparable X-Ray Opacity Dimension(if any):Width 5cm to 250cm & Length 5cm to 100Meter X (4 to 32)Ply Shelflife:3 Years Sterile or Non sterile:Non-Sterilized Brand Name(if registered under the Trade Marks Act, 1999):NIL
7	Generic Name:X-Ray Detectable Laparotomy Sponges IS 10829 Model No.:NIL Intended Use:The Laparotomy sponges is used in surgical procedures to absorb blood and other fluids as well as clean wounds. X-Ray Detectable thread allows easy to detect if the dressing materials left in the body Class of medical device:Class B Material of construction:Plain weave bleached, folded absorbent gauze and Monofilament or Multifilament Distinctly coloured X-Ray Detectable Yarn as per the specification IS 10829 Requirements. The X-Ray Detectable member consist of not less than 55 percent of barium sulphate giving a comparable X-Ray Opacity Dimension(if any):Width 20cm to 100cm, Length 20cm to 100cm, (4 to 32) Ply Shelflife:3 Years Sterile or Non sterile:Non-Sterilized Brand Name(if registered under the Trade Marks Act, 1999):NIL

8	Generic Name:X-Ray Detectable Gauze Swabs IS 10829 Model No.:NIL Intended Use:The X-Ray Detectable Gauze Swabs are used for wound dressing, padding, protection, blood spill and to applying antiseptic. X-Ray Detectable thread allows easy to detect if the dressing materials left in the body Class of medical device:Class B Material of construction:Plain weave bleached, folded absorbent gauze and Monofilament or Multifilament Distinctly coloured X-Ray Detectable Yarn as per the specification IS 10829 Requirements. The X-Ray Detectable member consist of not less than 55 percent of barium sulphate giving a comparable X-Ray Opacity Dimension(if any):Width 5cm to 25cm, Length 5cm to 25cm, (4 to 32) Ply Shelflife:3 Years Sterile or Non sterile:Non-Sterilized Brand Name(if registered under the Trade Marks Act, 1999):NIL
9	Generic Name:Absorbent Cotton Gauze BP 1988 Type 17 Model No.:NIL - Intended Use:The Absorbent Cotton Gauze is used cleaning, drying, moisture removal and dressing wounds during a medical treatment Class of medical device:Class B Material of construction:As per the specification BP 1988 Type 17 Standard Requirements Dimension(if any):Width 5cm to 180cm, Length 5cm to 100 Meters, Ply 4 to 32 Shelflife:3 Years Sterile or Non sterile:Non-Sterilized Brand Name(if registered under the Trade Marks Act, 1999):NIL
10	Generic Name:Dressing Pad (IHS) Model No.:NIL - Intended Use:The Dressing Pad is applied to wounds to promote healing and protect the wound form further harm Class of medical device:Class B Material of construction:A Layer of(250GSM to 350GSM)Absorbent Cotton (IS 16468) wrapped in an Absorbent Cotton Gauze (IS 758)(woven plain weave bleached gauze cloth) Dimension(if any):Width 5cm to 50cm, Length 5cm to 10 Meters Shelflife:3 Years Sterile or Non sterile:Non-Sterilized Brand Name(if registered under the Trade Marks Act, 1999):NIL

Place:

Date04-Jun-24

State Licensing Authority