



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/2022/000719

1. M/s Pinnacle Technologies, 201-Q-WING, NETAJI BUILDING, SION-MAHIM LINK ROAD, MAHIM (EAST) Vasai, Mumbai City, Maharashtra (India) - 400017 Telephone No.: 02224031718 FAX: 02224031718 has been licenced to manufacture for sale or for distribution the below listed medical device(s) at the premises situated at M/s Pinnacle Technologies, Gala No. 113, Building No. 28, HDIL Industrial park, Chandansar, Virar East, Palghar, Maharashtra (India) - 401304 Telephone No.: 09320638129 FAX: 09320638129

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	<p>Generic Name: Eye Drape (Sterile)</p> <p>Model No.: Incise drape mini - 10x15cm, 13x15cm, Eye drape with PE incise drape - 20x25cm, 40x50cm, 60x60cm, 70x70cm, 100x70cm, 100x100cm, 100x120cm, 100x130cm, Eye drape double layer - 100x70cm</p> <p>Intended Use: Eye drapes designed with a unique, U-shaped, fluid-containment pouch that helps reduce exposure during phacoemulsification and other fluid-intensive procedures and may be used for the left or right eye</p> <p>Class of medical device: Class B</p> <p>Material of construction: Non-Woven Fabric</p> <p>Dimension(if any): Small, Medium and Large</p> <p>Shelflife: 3 years</p> <p>Sterile or Non sterile: Sterilized</p> <p>Brand Name(if registered under the Trade Marks Act, 1999): NIL</p>

2	<p>Generic Name:Surgical gown (Sterile)</p> <p>Model No.:Non reinforced surgical gown - Small, medium, large, extra large,Reinforced surgical gown - Small, medium, large, extra large</p> <p>Intended Use:A sterile garment made of natural and/or synthetic materials intended for surgical procedures to help protect both the patient and operating room personnel from the transfer of microorganisms, body fluids, and particulate material.</p> <p>Class of medical device:Class B</p> <p>Material of construction:Non-Woven Fabric</p> <p>Dimension(if any):Small, Medium, Large, XL and XXL</p> <p>Shelflife:3 years</p> <p>Sterile or Non sterile:Sterilized</p> <p>Brand Name(if registered under the Trade Marks Act, 1999):NIL</p>
3	<p>Generic Name:Surgical Drape &amp; Drape Accessories</p> <p>Model No.:Leg u drape - 160x200cm,Arm O drape - 150x160cm,Leg O drape - 150x200cm, Arm O drape - 150x150cm,Major drape - 160x250cm,Camera cable cover - 15x250cm,Cling drape - 15x500cm,Gynac drape - 150x200cm,Laparoscopy drape - 60x250cm,Caesarean drape - 160x250cm,Plain towel /sheet - 120x75cm,120x100cm,120x150cm,120x210cm,Incise drape - Small, medium, large, extra large,Phaco machine cove - 100x75cm,,Microscope cover - 100x150cm,Adhesive towel - 50x75cm, 75x100cm</p> <p>Intended Use:A surgical drape &amp; drape accessories is a device made of natural or synthetic materials intended to be used as a protective patient covering to isolate a site of surgical incision from microbial &amp; other contamination.</p> <p>Class of medical device:Class B</p> <p>Material of construction:Non-Woven &amp; Melt-Blown</p> <p>Dimension(if any):Small, Medium and Large</p> <p>Shelflife:3 years</p> <p>Sterile or Non sterile:Sterilized</p> <p>Brand Name(if registered under the Trade Marks Act, 1999):NIL</p>

Place:

Date28-Dec-22

State Licensing Authority