

F NO :

Government of India  
Directorate General of Health Services  
Central Drugs Standard Control Organisation  
Ministry of Health and Family welfare

FREE SALE CERTIFICATE

FSC Number : FSC/MD/2023/000624

Dated : 18/12/2023

This is to certify that M/s. Pinnacle Technologies ,Pinnacle Technologies situated at address Gala No. 113, Building No. 28, HDIL Industrial park, Chandansar, Virar East ,Palghar Maharashtra , 401304,09320638129, India is holding Manufacturing License no. MFG/MD/2022/000719 issued on 28-DEC-2022 Under this license, the said firm is permitted to manufacture the products for their manufacture and sale in domestic market as per Indian Law and for export as per law of importing country (ies):-

Name of the products with their product name and dimensions if any mentioned below :

S.NO	Medical Device Details
1	<ol style="list-style-type: none"><li>1. Generic Name :Eye Drape (Sterile)</li><li>2. Brand Name :NIL</li><li>3. Notified Category :OthersOphthalmology</li><li>4. Class of Medical Device :Class B</li><li>5. Shelf life :3 years</li><li>6. Sterile/Non-Sterile:Sterilized</li><li>7. 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</li><li>8. Material of Construction: Non-Woven Fabric</li><li>9. Dimension: Small, Medium and Large</li><li>10. Model/Catalogue No./Name :Incise drape mini - 10x15cm,13x15cm, Eye drape with PE incise drape - 20x25cm, 40x50cm, 60x60cm, 70x70cm,100x70cm,100x100cm, 100x120cm, 100x130cm, Eye drape double layer - 100x70cm</li></ol>

2	<ol style="list-style-type: none"> <li>1. Generic Name :Surgical gown (Sterile)</li> <li>2. Brand Name :NIL</li> <li>3. Notified Category :OthersPersonal Protective Equipment</li> <li>4. Class of Medical Device :Class B</li> <li>5. Shelf life :3 years</li> <li>6. Sterile/Non-Sterile:Sterilized</li> <li>7. 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.</li> <li>8. Material of Construction: Non-Woven Fabric</li> <li>9. Dimension: Small, Medium, Large, XL and XXL</li> <li>10. Model/Catalogue No./Name :Non reinforced surgical gown - Small, medium, large, extra large,Reinforced surgical gown - Small, medium, large, extra large</li> </ol>
3	<ol style="list-style-type: none"> <li>1. Generic Name :Surgical Drape &amp; Drape Accessories</li> <li>2. Brand Name :NIL</li> <li>3. Notified Category :OthersPersonal Protective Equipment</li> <li>4. Class of Medical Device :Class B</li> <li>5. Shelf life :3 years</li> <li>6. Sterile/Non-Sterile:Sterilized</li> <li>7. 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.</li> <li>8. Material of Construction: Non-Woven &amp; Melt-Blown</li> <li>9. Dimension: Small, Medium and Large</li> <li>10. Model/Catalogue No./Name :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</li> </ol>
4	<ol style="list-style-type: none"> <li>1. Generic Name :Eye pad (sterile)</li> <li>2. Brand Name :NIL</li> <li>3. Notified Category :OthersPersonal Protective Equipment</li> <li>4. Class of Medical Device :Class B</li> <li>5. Shelf life :3 years</li> <li>6. Sterile/Non-Sterile:Sterilized</li> <li>7. Intended Use :to cover the eye to protect it and/or absorb secretions Sterile</li> <li>8. Material of Construction: Surgical cotton, nonwoven spunlace fabric</li> <li>9. Dimension: 5x7.5cm</li> <li>10. Model/Catalogue No./Name :NIL</li> </ol>
5	<ol style="list-style-type: none"> <li>1. Generic Name :Eye dressing pad (sterile)</li> <li>2. Brand Name :NIL</li> <li>3. Notified Category :OthersPersonal Protective Equipment</li> <li>4. Class of Medical Device :Class B</li> <li>5. Shelf life :3 years</li> <li>6. Sterile/Non-Sterile:Sterilized</li> <li>7. Intended Use :to cover the eye to protect it and/or absorb secretions Sterile</li> <li>8. Material of Construction: Surgical cotton, nonwoven spunlace fabric, adhesive coated spunlace snonwoven fabric</li> <li>9. Dimension: 5x7.5cm</li> <li>10. Model/Catalogue No./Name :NIL</li> </ol>

6	<ol style="list-style-type: none"> <li>1. Generic Name :Transparent film Dressing with pad(sterile)</li> <li>2. Brand Name :NIL</li> <li>3. Notified Category :OthersPersonal Protective Equipment</li> <li>4. Class of Medical Device :Class B</li> <li>5. Shelf life :3 years</li> <li>6. Sterile/Non-Sterile:Sterilized</li> <li>7. Intended Use :The Intended use of transparent film dressings is to allow a doctor or physician to actively see and monitor a wound without being exposed to the elements. Additionally, these surgical wound dressing types of bandages protect against liquid, water, and bacteria from entering the damage.</li> <li>8. Material of Construction: Polyurethane film , Release paper, medical grade adhesive, Non adherent pad</li> <li>9. Dimension: 6x7cm, 10x12cm, 10x25cm, 15x20cm, 20x30cm</li> <li>10. Model/Catalogue No./Name :NIL</li> </ol>
7	<ol style="list-style-type: none"> <li>1. Generic Name :Non Woven Island Adhesive Dressing with Pad (sterile)</li> <li>2. Brand Name :NIL</li> <li>3. Notified Category :OthersPersonal Protective Equipment</li> <li>4. Class of Medical Device :Class B</li> <li>5. Shelf life :3 years</li> <li>6. Sterile/Non-Sterile:Sterilized</li> <li>7. Intended Use :Non-Woven Island Dressing is for use on light to moderate draining wounds, superficial and partial-thickness wounds, IV catheter sites, incision sites, cuts and lacerations and to secure or cover devices.</li> <li>8. Material of Construction: Non woven fabric , Release paper, medical grade adhesive, non adherent pad</li> <li>9. Dimension: 5x7.2cm, 6x8cm, 10x10cm, 10x15cm, 10x20cm, 10x25cm, 10x30cm</li> <li>10. Model/Catalogue No./Name :NIL</li> </ol>

Competent Authority