



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/2026/000311**

1. **M/s COLDCHAIN CONTROLS, 96A, 3rd Floor, Sri Ganpathy Complex, A K Nagar, Sai Baba Colony, Coimbatore COIMBATORE, Coimbatore, Tamil Nadu (India) - 641011 Telephone No.: 0422-2446016 FAX: 0422-2446016** has been licenced to manufacture for sale or for distribution the below listed medical device(s) at the premises situated at **M/s Coldchain Controls, S.F No. 280/1B, Irugurkarar Thottam, Selvalakshmiapuram, Sarguna Mill Compound Road, Kannampalayam, Coimbatore, Tamil Nadu, 641402., Coimbatore, Tamil Nadu (India) - 641402 Telephone No.: 9442216016 FAX: 9442216016**
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><b>Generic Name :</b> Icelined Refrigerator <b>Model No. :</b> CC 150 EC ILR - Net capacity 90 Litres ,CC 200 EC ILR - Net capacity 110 Litres ,CC 300 EC ILR - Net capacity 170 Litres ,CC 240 EC ILR - Gross Capacity 450 Litres , CC 307 EC ILR - Gross Capacity 550 Litres ,CC 500 EC ILR - Net capacity 350 Litres ,CC 800 EC ILR - Net capacity 600 Litres <b>Intended Use :</b> An ice-lined refrigerator is a refrigeration device that uses a combination of ice and an insulated compartment to maintain a consistent and low temperature for the storage of vaccines and other medical products. It relies on the principle of thermal energy storage to preserve the required temperature for an extended period, even in the absence of a continuous power supply. <b>Class of medical device :</b> Class B <b>Material of construction :</b> Temperature Range +2°C to +8°C, Power supply: 220V-240V, Rated frequency: 50Hz, 304 Grade Stainless Steel, CFC-Polyethylene Insulation Material, Outer cabinet sheet Inner lining sheet (stainless) Insulation foam (PUF) Ice-lining stainless tanks Phase-change Compressor Condenser coil + fan Evaporator coil Refrigerant Copper tubing Filter-drier Thermostat / controller for (ILR) Temperature sensors / probes IoT data logger (optional) Alarm module Power supply &amp; wiring Defrost / drain system Door gasket / seal Hinges &amp; locks Vaccine baskets / racks Shelves / supports Castor wheels or stand Paint &amp; coating materials Insulation adhesives / sealants Mounting hardware Electrical components Power backup (optional) Documentation &amp; labeling Test &amp; commissioning supplies Packaging materials Capillary Tube . <b>Dimension(if any) :</b> <b>Shelflife :</b> Nil <b>Sterile or Non sterile :</b> Non-Sterilized <b>Accessory Name :</b> NIL <b>Brand Name(if registered under the Trade Marks Act, 1999) :</b> NIL</p>

2	<p><b>Generic Name :</b> Deep Freezer</p> <p><b>Model No. :</b> CC 150 DF ILDF - Net capacity 90 Litres ,CC 200 DF ILDF - Net Capacity 110 Litres ,CC 300 DF ILDF - Net Capacity 170 Litres ,CC 240 DF ILDF - Net Capacity 450 Litres ,CC 307 DF ILDF - Net Capacity 550 Litres ,CC 500 DF ILDF - Net Capacity 350 Litres ,CC 800 DF ILDF - Net Capacity 600 Litres</p> <p><b>Intended Use :</b> Deep Freezers are designed for storage of biological samples, vaccines, serums, medical specimens at sub-zero temperatures. These chambers are ideal for long term storage &amp; manufactured as per GMP norms. These chambers meet all critical requirements in the industry.</p> <p><b>Class of medical device :</b> Class B</p> <p><b>Material of construction :</b> Temperature range -15°C to -25°C, Power supply: 220V-240V, Rated frequency: 50Hz, 304 Grade Stainless Steel,CFC-Polyethylene Insulation Material, Outer cabinet sheet Inner lining sheet (stainless) Insulation foam (PUF) Ice-lining stainless tanks Phase-change Compressor Condenser coil + fan Evaporator coil Refrigerant Copper tubing Filter-drier Thermostat / controller for (DF) Temperature sensors / probes IoT data logger (optional) Alarm module Power supply &amp; wiring Defrost / drain system Door gasket / seal Hinges &amp; locks Vaccine baskets / racks Shelves / supports Castor wheels or stand Paint &amp; coating materials Insulation adhesives / sealants Mounting hardware Electrical components Power backup (optional) Documentation &amp; labeling Test &amp; commissioning supplies Packaging materials Capillary Tube</p> <p><b>Dimension(if any) :</b></p> <p><b>Shelflife :</b> NIL</p> <p><b>Sterile or Non sterile :</b> Non-Sterilized</p> <p><b>Accessory Name :</b> NIL</p> <p><b>Brand Name(if registered under the Trade Marks Act, 1999) :</b> NIL</p>
3	<p><b>Generic Name :</b> Blood Storage Refrigerator</p> <p><b>Model No. :</b> CC 150 BBR - Net Capacity 90 Litres ,CC 200 BBR - Net Capacity 110 Litres , CC 300 BBR - Net Capacity 170 Litres ,CC 240 BBR - Net Capacity 450 Litres ,CC 307 BBR - Net Capacity 550 Litres ,CC 500 BBR - Net Capacity 350 Litres ,CC 800 BBR - Net Capacity 600 Litres</p> <p><b>Intended Use :</b> These are devices intended for medical purposes that are used to preserve blood and blood products by storing them at cold or freezing temperatures.</p> <p><b>Class of medical device :</b> Class B</p> <p><b>Material of construction :</b> Temperature Range +2°C to +6°C, Power supply: 220V-240V, Rated frequency: 50Hz, 304 Grade Stainless Steel,CFC-Polyethylene Insulation Material, Outer cabinet sheet Inner lining sheet (stainless) Insulation foam (PUF) Ice-lining stainless tanks Phase-change Compressor Condenser coil + fan Evaporator coil Capillary Tube Refrigerant Copper tubing Filter-drier Sight glass Thermostat / controller for (BBILR) Temperature sensors / probes IoT data logger (optional) Alarm module Power supply &amp; wiring Defrost / drain system Door gasket / seal Hinges &amp; locks Vaccine baskets / racks Shelves / supports Castor wheels or stand Paint &amp; coating materials Insulation adhesives / sealants Mounting hardware Electrical components Power backup (optional) Documentation &amp; labeling Test &amp; commissioning supplies Packaging materials</p> <p><b>Dimension(if any) :</b></p> <p><b>Shelflife :</b> Nil</p> <p><b>Sterile or Non sterile :</b> Non-Sterilized</p> <p><b>Accessory Name :</b> NIL</p> <p><b>Brand Name(if registered under the Trade Marks Act, 1999) :</b> NIL</p>

Place:

Date: 13-May-26

State Licensing Authority