



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/2024/000558**

1. **M/s Newtronic Lifecare Equipment Private Limited, Plot No. 1205 1206, Newtronic Lifecare Equipment Private Limited, Road 13, G.I.D.C Valsad, Valsad, Gujarat (India) - 396171 Telephone No.: 8291958902, 9920592207 FAX: 22-2867 6059** has been licenced to manufacture for sale or for distribution the below listed medical device(s) at the premises situated at **M/s Newtronic Lifecare Equipment Private Limited, Plot No. 105 & 1206, Phase 03, Road 13, G.I.D.C. , Umbergaon, Valsad, Gujarat (India) - 396171 Telephone No.: 8291958902 FAX: 260-2561411**

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> PLASMA FREEZERS</p> <p><b>Model No.:</b> NLPF7MI - CapacityCuft. 200, Internal Chamber W*D*H (mm) 550X 545 X 670, External Chamber W*D*H (mm) 835 X 870 X 1625, Number of Shelves 2, Equipment Weight (Kg) 150Kg, NLPF11MI - CapacityCuft. 300, Internal Chamber W*D*H (mm) 550 X 610 X 900, External Chamber W*D*H (mm) 835 X 935 X 1910, Number of Shelves 3, Equipment Weight (Kg) 200Kg, NLPF14MI - CapacityCuft. 300, Internal Chamber W*D*H (mm) 550 X 730 X 1000, External Chamber W*D*H (mm) 835 X 1055 X 2010, Number of Shelves 4, Equipment Weight (Kg) 250Kg, Newtronic manufacture Customized Models as per customer requirements also - Customized Models as per customer requirements and specifications</p> <p><b>Intended Use:</b> Newtronic Plasma Freezer is designed to maintain uniform Temperature with minimum breakdowns. The technology ensures precise performance for the ultimate protection of Plasma from temperature drifts. The intended use of plasma freezers is to provide a controlled and consistently low-temperature environment for the safe and long-term storage of blood plasma and related blood products. These specialized freezers are designed to maintain temperatures typically between 30°C to - 40°C to preserve the quality, integrity, and safety of plasma. Plasma freezers are used in healthcare facilities, blood banks, and laboratories to ensure that plasma products remain suitable for transfusion, diagnostic testing, and research purposes.</p> <p><b>Class of medical device:</b> Class B</p> <p><b>Material of construction:</b> Inner body: Stainless Steel (5S 304) , Outer body: Pre Coated Galvanized Iron Insulation : High density CFC free PUF insulation</p> <p><b>Dimension(if any):</b> Dimensions of models are modularized based on customer requirements within defined liter capacity. Some models under this grouping family have external chambers dimensions (W*D*H (mm) as follows: NLPF7MI (835 X 870 X 1625), NLPF11MI (835 X 935 X 1910), NLPF14MI (835 X 1055 X 2010) etc.</p> <p><b>Shelflife:</b> NIL</p> <p><b>Sterile or Non sterile:</b> Non-Sterilized</p> <p><b>Brand Name(if registered under the Trade Marks Act, 1999):</b> NEWTRONIC</p>

2	<p><b>Generic Name:</b>BLOOD BANK REFRIGERATORS</p> <p><b>Model No.:</b>Newtronic manufacture Customized Models as per customer requirements also - Customized Models as per customer requirements and specifications,NLBR11S/NLBR11MI - Capacity Liter 300L, Internal Size W*D*H (mm) 600 X 500 X 1000, External Size W*D*H (mm) 700 X 653 X 1655, Single Drawer Blood Bag Capacity 60 BLOOD BAGS, All Drawer Blood Bag Capacity 240 BLOOD BAGS, Number of Shelves 4, Equipment Weight (Kg) 200Kg., NLBR14S/NLBR14MI - Capacity Liter 400L, Internal Size W*D*H (mm) 600 X 670 X 1000, External Size W*D*H (mm) 700 X 823 X 1655, Single Drawer Blood Bag Capacity 80 BLOOD BAGS, All Drawer Blood Bag Capacity 320 BLOOD BAGS, Number of Shelves 4, Equipment Weight (Kg) 250Kg.,NLBR7S/NLBR7MI - Capacity Liter 200L, Internal Size W*D*H (mm) 560 X 450 X 800, External Size W*D*H (mm) 660 X 603 X 1415, Single Drawer Blood Bag Capacity 39 BLOOD BAGS, All Drawer Blood Bag Capacity 117 BLOOD BAGS, Number of Shelves 3, Equipment Weight (Kg) 150Kg.</p> <p><b>Intended Use:</b>Blood Bank Refrigerators is intended to provide a controlled and consistently low-temperature environment for the safe and long-term storage of blood platelets, plasma and related blood products. These specialized freezers are designed to maintain temperatures typically between 2°C to 6°C to preserve the quality, integrity, and safety of blood bank related products. The blood bank refrigerator is an essential piece of equipment in the immuno-hematology department and provides safe and convenient storage of whole blood, blood components (e.g, blood cells, plasma) and reagents. Blood bank refrigerators ensure freshness and integrity of blood and blood components. Our Blood Bank Refrigerators meet the highest regulatory requirements.</p> <p><b>Class of medical device:</b>Class B</p> <p><b>Material of construction:</b>Inner Cabinet (MOC): Stainless Steel (304) Outer Cabinet: G. I. Powder Coated (0.6 mm) Insulation: PUF insulation (Poly Urethane foam). Door: Full length glass door with door seal gasket and lock.</p> <p><b>Dimension(if any):</b>Dimensions of models are modularized based on customer requirements within defined liter capacity. Some models under this grouping family have external chambers dimensions (W*D*H (mm) as follows: NLBR7MI (1415 x 660 x 605), NLBR11M (1655mm x 700mmx 655mm), NLBR14M (1655mm x 700mm x 825) etc.</p> <p><b>Shelflife:</b>NIL</p> <p><b>Sterile or Non sterile:</b>Non-Sterilized</p> <p><b>Brand Name(if registered under the Trade Marks Act, 1999):</b>NEWTRONIC</p>
3	<p><b>Generic Name:</b>MEDICAL REFRIGERATORS</p> <p><b>Model No.:</b>NLMR7G - CapacityCuft. 200L, Internal Chamber W*D*H (mm) 560 X 450 X 800, External Chamber W*D*H (mm) 660 X 603 X 1415 , Number of Shelves 3, Equipment Weight (Kg) 150Kg.,NLMR11G - CapacityCuft. 300L, Internal Chamber W*D*H (mm) 600 X 500 X 1000, External Chamber W*D*H (mm) 700 X 653 X 1655 , Number of Shelves 4, Equipment Weight (Kg) 200Kg.,NLMR14G - CapacityCuft. 400L, Internal Chamber W*D*H (mm) 600 X 670 X 1000, External Chamber W*D*H (mm) 700 X 823 X 1655 , Number of Shelves 4, Equipment Weight (Kg) 250Kg.,Newtronic manufacture Customized Models as per customer requirements also - Customized Models as per customer requirements and specifications</p> <p><b>Intended Use:</b>Medical Refrigerator is engineered with a highly efficient vertical and horizontal airflow system to provide maximum temperature uniformity. designed to maintain temperatures typically between 2 to 8°C(upper) &amp; -10 to -25°C to preserve the quality, integrity, and safety of the storage of blood products and other medical and scientific products</p> <p><b>Class of medical device:</b>Class B</p> <p><b>Material of construction:</b>Inner body is made of Stainless Steel 304 (0.6mm) and Outer body is G. I. Powder Coated (0.6 mm) PUF insulation between outer chamber and inner chamber. Purn Sanket Type Temperature Sensors ( -30°C to 300°C) Door: Full length glass door with door seal gasket and lock.</p> <p><b>Dimension(if any):</b>Dimensions of models are modularized based on customer requirements within defined liter capacity. Some models under this grouping family have external chambers dimensions (H*W*D (mm) as follows: NLMR11GI (1675 x 700 x 615), NLMR14G (1675 x 700 x 785)</p> <p><b>Shelflife:</b>NIL</p> <p><b>Sterile or Non sterile:</b>Non-Sterilized</p> <p><b>Brand Name(if registered under the Trade Marks Act, 1999):</b>NEWTRONIC</p>

Digitally signed by Dr.  
H.G.KOSHIA  
DN: cn=Dr. H.G.KOSHIA,  
o=Food and Drugs Control  
Administration,  
ou=Commissioner,  
email=comfdca@gujarat.gov.  
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Date: 2024.08.02 18:35:09  
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4	<p><b>Generic Name:</b>ULTRA-LOW TEMPERATURE FREEZERS</p> <p><b>Model No.:</b>NLUF04MI - CapacityCuft. 4, 100L, Internal Chamber H*W*D (mm) 514 X 450 X 439, External Chamber H*W*D (mm) 820 X 1066 X 742, Number of Shelves 2, Equipment Weight (Kg) 145Kg.,NLUF07MI - CapacityCuft. 7, 200L, , Internal Chamber H*W*D (mm) 767 X 470 X 570, External Chamber 1552 X 840 X 940 , Number of Shelves 2 , Equipment Weight (Kg) 205Kg, NLUF14MI - CapacityCuft. 14, 398L, Internal Chamber H*W*D (mm) 1266 X 404 X 696, External Chamber H*W*D (mm) 1947 X 788 X 1041, Number of Shelves 2, Equipment Weight (Kg) 252Kg.,NLUF19MI - CapacityCuft. 19, 528L, Internal Chamber, H*W*D (mm) 1266 X 585 X 696, External Chamber H*W*D (mm) 1947 X 930 X 1041, Number of Shelves 2, Equipment Weight (Kg) 286Kg.,NLUF23MI - CapacityCuft. 23, 678L, Internal Chamber, W*D*H (mm) 1286 X 750 X 696, External Chamber H*W*D (mm)1955 X 1090 X 1025, Number of Shelves 4, Equipment Weight (Kg) 330Kg.,NLUF27MI - CapacityCuft. 27, 778L, Internal Chamber W*D*H (mm) 1286 X 865 X 696, External Chamber H*W*D (mm) 1955 X 1205 X 1025, Number of Shelves 4, Equipment Weight (Kg) 380Kg.,NLUF30MI - CapacityCuft. 30, 858L, Internal Chamber, W*D*H (mm) 1378 X 877 X 696, External Chamber H*W*D (mm) 2005 X 1217 X 1025, Number of Shelves 4, Equipment Weight (Kg) 390Kg,NLUF36MI - CapacityCuft. 36, 1008L, Internal Chamber, W*D*H (mm) 1378 X 1022 X 696, External Chamber, H*W*D (mm) 2002 X 1362 X 1025, Number of Shelves 4, Equipment Weight (Kg) 430Kg.,Newtronic manufacture Customized Models as per customer requirements also - Customized Models as per customer requirements and specifications</p> <p><b>Intended Use:</b>Ultra Low Temperature Freezer is intended to provide a controlled and consistently low-temperature environment for the safe and long-term storage of samples and related products. These specialized freezers are designed to maintain cryogenic temperatures typically between -10°C to - 86°C to preserve the quality, integrity, and safety of samples/products.</p> <p><b>Class of medical device:</b>Class B</p> <p><b>Material of construction:</b>Inner Cabinet (MOC): Stainless Steel (304) Outer Cabinet: Pre coated GI Insulation : PUF insulation (Poly Urethane foam). Outer Door: Epoxy polyester powder spray coated steel plate. Ektexine: Epoxy polyester powder spray coated steel plate. Inner Door: Epoxy polyester powder spray coated Aluminum plate. Insulation: VIP+Rigid Polyurethane; Compressor is Hermetic;</p> <p><b>Dimension(if any):</b>Dimensions of models are modularized based on customer requirements within defined liter capacity. Some models under this grouping family have external chambers dimensions (H*W*D (mm) as follows: NLUF04MI- (820 X 1066 X 742), NLUF07MI- (1552 X 840 X 940) , NLUF14MI- (1947 X 788 X 1041) , NLUF19MI- (1947 X 930 X 1041) , NLUF23MI – (1955 X 1090 X 1025) , NLUF27MI – (1955 X 1205 X 1025) , NLUF30MI – (2005 X 1217 X 1025), NLUF36MI – (2002 X 1362 X 1025), etc.</p> <p><b>Shelflife:</b>NIL</p> <p><b>Sterile or Non sterile:</b>Non-Sterilized</p> <p><b>Brand Name(if registered under the Trade Marks Act, 1999):</b>NEWTRONIC</p>
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Place: GANDHINAGAR

Date02-Aug-24

Digitally signed by Dr.  
H.G.KOSHIA  
DN: cn=Dr. H.G.KOSHIA,  
o=Food and Drugs Control  
Administration,  
ou=Commissioner,  
email=comfdca@gujarat.gov.in  
, c=IN  
Date: 2024.08.02 18:34:58  
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