



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/2022/000048

1. M/s Raja Ramanna Centre For Advanced Technology, Department Of Atomic Energy, Head, Industrial Accelerators Division, F-01, IMA Building, RRCAT, P.O.- CAT, IndoreIndore, Indore, Madhya Pradesh (India) - 452013 Telephone No.: 07312488587 FAX: 07312488550 has been licenced to manufacture for sale or for distribution the below listed medical device(s) at the premises situated at M/s Raja Ramanna Centre For Advanced Technology, Department of Atomic Energy, Government of India, Agricultural Radiation Processing Facility, Devi Ahilyabai Holkar Fruit and Vegetable Mandi Complex, Indore, Madhya Pradesh (India) - 452013 Telephone No.: 07312488587 FAX: 0731 2488550

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.

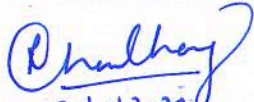
ANNEXURE

S.No.	Details Of Device(s)
1	<p>Generic Name:Surgical dressings Model No.:NIL</p> <p>Intended Use:Used in surgery to close the skin wounds, skin removal, Dressing-gel, dressing-permeable, moisture dressing, tracheostomy tube dressing, wound and burn dressings, hydrogel dressing, wound and burn, occlusive, adhesive bandages, gauge bandages, medical absorbent (fiber) bandages, orthosis (brace), or prosthesis procedures, spot-welded auxiliary hook, vascular reconstructions & wound closure procedures</p> <p>Class of medical device:Class B</p> <p>Material of construction:Cotton, non-woven sponges, medicated, hydrogel, hydro fiber, alginate Stainless steel, titanium, etc</p> <p>Dimension(if any):</p> <p>Shelflife:Till integrity of primary packaging is maintained</p> <p>Sterile or Non sterile:Sterilized</p> <p>Brand Name(if registered under the Trade Marks Act, 1999):NIL</p>

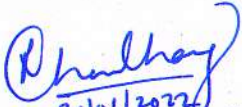

31/01/2022

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2	<p>Generic Name:Catheters pertaining to Gastroenterological procedures Model No.:NIL Intended Use:Used into rectal, biliary, esophageal, colonal, jejunostomy, stomach , peritoneal, endoscopic, colan related procedures Class of medical device:Class B Material of construction:PVC, PP, PVA, Polyamides, Polyurethane, PTFE, POE, PPH, Polyetherimide, Polyester, Silicon, etc Dimension(if any): Shelflife:Till integrity of primary packaging is maintained Sterile or Non sterile:Sterilized Brand Name(if registered under the Trade Marks Act, 1999):NIL</p>
3	<p>Generic Name:Catheters pertaining to Urological/ Nephrological procedures Model No.:NIL Intended Use:Used into the nephrostomy, urethral, dialysis, upper & lower urinary tract related procedures. Class of medical device:Class B Material of construction:PVC, PP, PVA, Polyamides, Polyurethane, PTFE, POE, PPH, Polyetherimide, Polyester, Silicon, etc. Dimension(if any): Shelflife:Till integrity of primary packaging is maintained Sterile or Non sterile:Sterilized Brand Name(if registered under the Trade Marks Act, 1999):NIL</p>
4	<p>Generic Name:Catheters pertaining to Cardio-vascular procedures Model No.:NIL Intended Use:Used into the angiographic, arterial, intravenous, hemodialysis, subclavian, umbical artery, heart-lungs related procedure Class of medical device:Class B Material of construction:PVC, PP, PVA, Polyamides, Polyurethane, PTFE, POE, PPH, Polyetherimide, Polyester, Silicon, etc. Dimension(if any): Shelflife:Till integrity of primary packaging is maintained Sterile or Non sterile:Sterilized Brand Name(if registered under the Trade Marks Act, 1999):NIL</p>
5	<p>Generic Name:Catheters pertaining to Respiratory procedures Model No.:NIL Intended Use:Used into the tracheostomy, bronchography, nasal, cervical, endotracheal related procedures Class of medical device:Class B Material of construction:PVC, PP, PVA, Polyamides, Polyurethane, PTFE, POE, PPH, Polyetherimide, Polyester, Silicon, etc. Dimension(if any): Shelflife:Till integrity of primary packaging is maintained Sterile or Non sterile:Sterilized Brand Name(if registered under the Trade Marks Act, 1999):NIL</p>


31.11.2022
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6	<p>Generic Name:Catheters pertaining to Gynecological procedures Model No.:NIL Intended Use:Used in to the treatment of abscesses and cysts of the hartholin gland, salpngography, ultrasonic, IVF related procedures Class of medical device:Class B Material of construction:PVC, PP, PVA, Polyamides, Polyurethane, PTFE, POE, PPH, Polyetherimide, Polyester, Silicon, etc. Dimension(if any): Shelflife:Till integrity of primary packaging is maintained Sterile or Non sterile:Sterilized Brand Name(if registered under the Trade Marks Act, 1999):NIL</p>
7	<p>Generic Name:Catheters pertaining to Neurological procedures Model No.:NIL Intended Use:Used into the spinal, anesthetic, neurological bladder or spinal cord injury procedures Class of medical device:Class B Material of construction:PVC, PP, PVA, Polyamides, Polyurethane, PTFE, POE, PPH, Polyetherimide, Polyester, Silicon, etc. Dimension(if any): Shelflife:Till integrity of primary packaging is maintained Sterile or Non sterile:Sterilized Brand Name(if registered under the Trade Marks Act, 1999):NIL</p>
8	<p>Generic Name:Catheters pertaining to ENT & ophthalmological procedures Model No.:NIL Intended Use:Used into the Eustachian tube patency, tonsils stones, ear and eye related surgical procedures Class of medical device:Class B Material of construction:PVC, PP, PVA, Polyamides, Polyurethane, PTFE, POE, PPH, Polyetherimide, Polyester, Silicon, etc. Dimension(if any): Shelflife:Till integrity of primary packaging is maintained Sterile or Non sterile:Sterilized Brand Name(if registered under the Trade Marks Act, 1999):NIL</p>
9	<p>Generic Name:Catheters pertaining to Orthodontic procedures Model No.:NIL Intended Use:Used into the orthodontic related procedures Class of medical device:Class B Material of construction:PVC, PP, PVA, Polyamides, Polyurethane, PTFE, POE, PPH, Polyetherimide, Polyester, Silicon, etc. Dimension(if any): Shelflife:Till integrity of primary packaging is maintained Sterile or Non sterile:Sterilized Brand Name(if registered under the Trade Marks Act, 1999):NIL</p>



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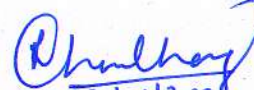
10	<p>Generic Name:Transfusion set Model No.:NIL Intended Use:Used to administer blood/drugs to a patient's vascular system through a vascular access device and used as part of a system for the infusion of fluids/medications in medical applications. Class of medical device:Class B Material of construction:PVC, polyacetate plastic, ABS (Acrylonitrile Butadiene Styrene), HDPE, PP, Silicon, etc. Dimension(if any): Shelflife:Till integrity of primary packaging is maintained Sterile or Non sterile:Sterilized Brand Name(if registered under the Trade Marks Act, 1999):NIL</p>
1 1	<p>Generic Name:Syringes- surgical, Gastroenterological, Insulin, Gynecological, Dental, & Dermatological Model No.:NIL Intended Use:Used for administration of medication, injection of fluids into, or withdraw fluids/blood form, parts of the body Class of medical device:Class B Material of construction:PVC, PP, PVA, Polyamides, Polyurethane, PTFE, POE, PPH, Polyetherimide, Polyester, Silicon etc. Dimension(if any): Shelflife:Till integrity of primary packaging is maintained Sterile or Non sterile:Sterilized Brand Name(if registered under the Trade Marks Act, 1999):NIL</p>
12	<p>Generic Name:Needles- (Dental, Neurological, Respiratory, surgical, cardio-vascular, Gastroenterological, Insulin, Gynecological & Dermatological) Model No.:NIL Intended Use:Used for administration of medication, injection of fluids into, or withdraw fluids form, parts of the body Class of medical device:Class B Material of construction:PVC, PP, PVA, Polyamides, Polyurethane, PTFE, POE, PPH, Polyetherimide, Polyester, Silicon, SS etc. Dimension(if any): Shelflife:Till integrity of primary packaging is maintained Sterile or Non sterile:Sterilized Brand Name(if registered under the Trade Marks Act, 1999):NIL</p>
13	<p>Generic Name:Cannula Model No.:NIL Intended Use:These devices used to provide for the infusion of fluids, drugs, and/or blood components, or to facilitate the placement of Vascular Access devices and used in neurosurgical procedures, cardio-surgical procedures, and dialysis procedures. Class of medical device:Class B Material of construction:PVC, PP, PVA, Polyamides, Polyurethane, PTFE, POE, PPH, Polyetherimide, Polyester, Silicon, SS Dimension(if any): Shelflife:Till integrity of primary packaging is maintained Sterile or Non sterile:Sterilized Brand Name(if registered under the Trade Marks Act, 1999):NIL</p>

14	<p>Generic Name:Scalp Vein Set Model No.:NIL Intended Use:Intended to be used for insertion into the patient's vascular system (single use only) as an in-dwelling device to administer fluids intravenously or to sample blood. Class of medical device:Class B Material of construction:PVC, Stainless Steel, Silicon, Epoxy, PP, ABS (Acrylonitrile Butadiene styrene) Dimension(if any): Shelflife:Till integrity of primary packaging is maintained Sterile or Non sterile:Sterilized Brand Name(if registered under the Trade Marks Act, 1999):NIL</p>
15	<p>Generic Name:Dermatological & Plastic surgery related devices Model No.:NIL Intended Use:Used for temporary receptacle for an organ during surgical procedures, used in surgical covering and subcutaneous surgical procedures. Class of medical device:Class B Material of construction:PVC, PP, PVA, Polyamides, Polyurethane, PTFE, POE, PPH, Polyetherimide, Polyester, Silicon, etc. Dimension(if any): Shelflife:Till integrity of primary packaging is maintained Sterile or Non sterile:Sterilized Brand Name(if registered under the Trade Marks Act, 1999):NIL</p>

Place:

Date 31-Jan-22




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