



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/2020/000293

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	Generic Name:Surgical Dressing material Model No.:NIL Intended Use:Used for applying medication to, or absorbing body fluids Class of medical device:Class A Material of construction:Cotton, non-woven fabric 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
2	Generic Name:Catheter Model No.:NIL Intended Use:A catheter (for adults) passed through the nares and advanced to the depth of the nasopharynx to remove air choke or obstruction. A Resuscitator Class of medical device:Class A Material of construction:Plastic polymers, silicone, latex rubber and polyvinyl chloride or PVC 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

3	<p>Generic Name:Specimen Receptacles  Model No.:NIL  Intended Use:Used as a specimen receptacle  Class of medical device:Class A  Material of construction:Polystyrene/ Polypropylene/PVC  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:Disposable Perfusion Sets  Model No.:NIL  Intended Use:It can be used to connect to a perfusion sets or catheter infusion for infusion of contract media etc.  Class of medical device:Class A  Material of construction:Plastic polymers, silicone, latex rubber, natural rubber, polyamides, polyvinyl acetates and polyvinyl chloride or PVC  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:Umbilical occlusion device  Model No.:NIL  Intended Use:These devices may be a clip, tie, tape, or other article used to close the blood vessels in the umbilical cord of a newborn infant.  Class of medical device:Class A  Material of construction:Plastic polymers, silicone, latex rubber, natural rubber, polyamides, polyvinyl acetates and polyvinyl chloride or PVC  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>
6	<p>Generic Name:Bolster Suture  Model No.:NIL  Intended Use:Non-latex plastic bolsters are used to hinder pressure of any temporary suture against the body during surgery.  Class of medical device:Class A  Material of construction:Plastic polymers, silicone, natural rubber, polyamides, polyvinyl acetates and polyvinyl chloride or PVC  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 02-Dec-20

State Licensing Authority



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## 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/2020/000293

Endorsement No. 1

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, 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	Generic Name:Alcohol Swabs Model No.:NIL Intended Use:It is a single use, sterile device containing 70% isopropyl alcohol used for scrubbing and allowing drying and will disinfect needless access sites prior to use. Class of medical device:Class A Material of construction:Non Woven, Woven, Cotton, polyester, alcohol 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

Place: *Bhopal*

Date:08-Jan-21

*Rajneesh*  
08/01/2021  
State Licensing Authority  
**Rajneesh Chowdhary**  
State Licensing Authority  
Food & Drugs Administration  
Madhya Pradesh