



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/2022/000597

1. M/s CML BIOTECH LTD, 4/434B, Karukutty-PO Angamaly, Ernakulam, Kerala (India) - 683576 Telephone No.: 0484-2454820, 2456820 FAX: 0484-2456820 has been licenced to manufacture for sale or for distribution the below listed medical device(s) at the premises situated at M/s CML BIOTECH LIMITED, Plot No 2, INKID Industrial Area, INKEL Business Park, Angamaly South P O, Ernakulam, Kerala (India) - 683573 Telephone No.: 0484-2456820, 0484-2457820 FAX: 0484 245 4820

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: Nylon Flocculated Nasopharyngeal (Nasal) Swab with breakable plastic stick Model No.: Nylon Flocculated Nasopharyngeal (Nasal) Swab with breakable plastic stick - N 80 – Breaking point at 80 mm from swab head Intended Use: For Collection & transport of microbiological specimen Class of medical device: Class A Material of construction: Moulded plastic stick with Flocculated Nylon tip Dimension (if any): Shelflife: 24 months Sterile or Non sterile: Sterilized Brand Name (if registered under the Trade Marks Act, 1999): Microzo
2	Generic Name: Nylon Flocculated Nasopharyngeal (Nasal) Swab with breakable plastic stick in PP Tube Model No.: Nylon Flocculated Nasopharyngeal (Nasal) Swab with breakable plastic stick in PP Tube - N 80 – Breaking point at 80 mm from swab head Intended Use: For Collection & transport of microbiological specimen Class of medical device: Class A Material of construction: Moulded plastic stick with Flocculated Nylon tip and kept in Polypropylene Tube Dimension (if any): Shelflife: 24 months Sterile or Non sterile: Sterilized Brand Name (if registered under the Trade Marks Act, 1999): Microzo

3	<p>Generic Name:Nylon Flocculated Oropharyngeal (Throat) Swab with breakable plastic stick Model No.:Nylon Flocculated Oropharyngeal (Throat) Swab with breakable plastic stick - T-80 – breaking point at 80 mm from swab head ,Nylon Flocculated Oropharyngeal (Throat) Swab with breakable plastic stick - T -30 –Breaking point at 30 mm from swab head Intended Use:For Collection & transport of microbiological specimen Class of medical device:Class A Material of construction:Moulded plastic stick with Flocculated Nylon tip Dimension(if any): Shelflife:24 months Sterile or Non sterile:Sterilized Brand Name(if registered under the Trade Marks Act, 1999):Microzo</p>
4	<p>Generic Name:Nylon Flocculated Oropharyngeal (Throat) Swab with breakable plastic stick in PP Tube Model No.:Nylon Flocculated Oropharyngeal (Throat) Swab with breakable plastic stick in PP Tube - T-80 – Breaking point at 80 mm from swab head,Nylon Flocculated Oropharyngeal (Throat) Swab with breakable plastic stick in PP Tube - T -30 – Breaking point at 30 mm from swab head Intended Use:For Collection & transport of microbiological specimen Class of medical device:Class A Material of construction:Moulded plastic stick with Flocculated Nylon tip and kept in polypropylene tube Dimension(if any): Shelflife:24 months Sterile or Non sterile:Sterilized Brand Name(if registered under the Trade Marks Act, 1999):Microzo</p>
5	<p>Generic Name:Combined pack of Nylon Flocculated Oropharyngeal(Throat) swab with breakable plastic stick & Nasopharyngeal (Nasal) Swab with breakable plastic stick Model No.:Combined pack of Nylon Flocculated Oropharyngeal(Throat) swab with breakable plastic stick and Nasopharyngeal (Nasal) Swab with breakable plastic stick - N80 + T80- One N 80 Nasal swab and one T 80 Throat swab,Combined pack of Nylon Flocculated Oropharyngeal(Throat) swab with breakable plastic stick and Nasopharyngeal (Nasal) Swab with breakable plastic stick - N80 +T 30- One N 80 Nasal swab and one T 30 Throat swab Intended Use:For Collection & transport of microbiological specimen Class of medical device:Class A Material of construction:Moulded plastic stick with Flocculated Nylon tip Dimension(if any): Shelflife:24 months Sterile or Non sterile:Sterilized Brand Name(if registered under the Trade Marks Act, 1999):Microzo</p>
6	<p>Generic Name:Polyester swab with Plastic Stick Model No.:NIL Intended Use:For Collection & transport of microbiological specimen Class of medical device:Class A Material of construction:Moulded plastic stick with Polyester Head Dimension(if any): Shelflife:24 months Sterile or Non sterile:Sterilized Brand Name(if registered under the Trade Marks Act, 1999):Microzo</p>
7	<p>Generic Name:Polyester swab with Plastic Stick in PP Tube Model No.:NIL Intended Use:For Collection & transport of microbiological specimen Class of medical device:Class A Material of construction:Moulded plastic stick with Polyester Head and kept in Polypropylene Tube Dimension(if any): Shelflife:24 months Sterile or Non sterile:Sterilized Brand Name(if registered under the Trade Marks Act, 1999):Microzo</p>

8	Generic Name:Nylon Flocculated Cervical Swab Model No.:Nylon Flocculated Cervical Swab - Plastic Swab Stick with breaking point at 40 mm from swab head Intended Use:For Collection & transport of microbiological specimen Class of medical device:Class A Material of construction:Moulded plastic stick with Flocculated Nylon tip Dimension(if any): Shelflife:24 months Sterile or Non sterile:Sterilized Brand Name(if registered under the Trade Marks Act, 1999):Microzo
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Place:

Date:16-Nov-22

State Licensing Authority

