



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/IVD/2022/000102

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.: 484 2454820, 2486820, FAX: 484 2454820

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: Vacuum Blood Collection Tube-K2 EDTA Tubes Model No.: Vacuum Blood Collection Tube-K2 EDTA Tubes - 1ml, Vacuum Blood Collection Tube-K2 EDTA Tubes - 2ml, Vacuum Blood Collection Tube-K2 EDTA Tubes - 3ml, Vacuum Blood Collection Tube-K2 EDTA Tubes - 4ml, Vacuum Blood Collection Tube-K2 EDTA Tubes - 5ml, Vacuum Blood Collection Tube-K2 EDTA Tubes - 6ml, Vacuum Blood Collection Tube-K2 EDTA Tubes - 7ml, Vacuum Blood Collection Tube-K2 EDTA Tubes - 8ml, Vacuum Blood Collection Tube-K2 EDTA Tubes - 9ml, Vacuum Blood Collection Tube-K2 EDTA Tubes - 10ml Intended Use: For Collection, storage and transport of blood specimen for diagnostic purpose Class of medical device: Class A Material of construction: PET tube with Bromo butyl rubber stopper with or without PE safety cap. Dimension (if any): Shelflife: 24 months Sterile or Non sterile: Sterilized Brand Name (if registered under the Trade Marks Act, 1999): Vacsure</p>

2	<p>Generic Name:Vacuum Blood Collection Tube-K3 EDTA Tubes Model No.:Vacuum Blood Collection Tube-K3 EDTA Tubes - 1ml,Vacuum Blood Collection Tube-K3 EDTA Tubes - 2ml,Vacuum Blood Collection Tube-K3 EDTA Tubes - 3ml,Vacuum Blood Collection Tube-K3 EDTA Tubes - 4ml,Vacuum Blood Collection Tube-K3 EDTA Tubes - 5ml,Vacuum Blood Collection Tube-K3 EDTA Tubes - 6ml, Vacuum Blood Collection Tube-K3 EDTA Tubes - 7ml,Vacuum Blood Collection Tube-K3 EDTA Tubes - 8ml,Vacuum Blood Collection Tube-K3 EDTA Tubes - 9ml,Vacuum Blood Collection Tube-K3 EDTA Tubes - 10ml Intended Use:For Collection ,storage and transport of blood specimen for diagnostic purpose Class of medical device:Class A Material of construction:PET tube with Bromo butyl rubber stopper with or without PE safety cap. Dimension(if any): Shelflife:24 months Sterile or Non sterile:Sterilized Brand Name(if registered under the Trade Marks Act, 1999):Vacsure</p>
3	<p>Generic Name:Vacuum Blood Collection Tube-Glucose (Fluoride-Oxalate) Tubes Model No.:Vacuum Blood Collection Tube-Glucose (Fluoride-Oxalate) Tubes - 1ml, Vacuum Blood Collection Tube-Glucose (Fluoride-Oxalate) Tubes - 2ml,Vacuum Blood Collection Tube-Glucose (Fluoride-Oxalate) Tubes - 3ml,Vacuum Blood Collection Tube-Glucose (Fluoride-Oxalate) Tubes - 4ml,Vacuum Blood Collection Tube-Glucose (Fluoride-Oxalate) Tubes - 5ml,Vacuum Blood Collection Tube-Glucose (Fluoride-Oxalate) Tubes - 6ml,Vacuum Blood Collection Tube-Glucose (Fluoride-Oxalate) Tubes - 7ml,Vacuum Blood Collection Tube-Glucose (Fluoride-Oxalate) Tubes - 8ml,Vacuum Blood Collection Tube-Glucose (Fluoride-Oxalate) Tubes - 9ml,Vacuum Blood Collection Tube-Glucose (Fluoride-Oxalate) Tubes - 10ml Intended Use:For Collection ,storage and transport of blood specimen for diagnostic purpose Class of medical device:Class A Material of construction:PET tube with Bromo butyl rubber stopper with or without PE safety cap. Dimension(if any): Shelflife:24 months Sterile or Non sterile:Sterilized Brand Name(if registered under the Trade Marks Act, 1999):Vacsure</p>
4	<p>Generic Name:Vacuum Blood Collection Tube-Glucose (Fluoride-K2 EDTA) Tubes Model No.:Vacuum Blood Collection Tube-Glucose (Fluoride-K2 EDTA) Tubes - 1ml, Vacuum Blood Collection Tube-Glucose (Fluoride-K2 EDTA) Tubes - 2ml,Vacuum Blood Collection Tube-Glucose (Fluoride-K2 EDTA) Tubes - 3ml,Vacuum Blood Collection Tube-Glucose (Fluoride-K2 EDTA) Tubes - 4ml,Vacuum Blood Collection Tube-Glucose (Fluoride-K2 EDTA) Tubes - 5ml,Vacuum Blood Collection Tube-Glucose (Fluoride-K2 EDTA) Tubes - 6ml,Vacuum Blood Collection Tube-Glucose (Fluoride-K2 EDTA) Tubes - 7ml,Vacuum Blood Collection Tube-Glucose (Fluoride-K2 EDTA) Tubes - 8ml,Vacuum Blood Collection Tube-Glucose (Fluoride-K2 EDTA) Tubes - 9ml,Vacuum Blood Collection Tube-Glucose (Fluoride-K2 EDTA) Tubes - 10ml Intended Use:For Collection ,storage and transport of blood specimen for diagnostic purpose Class of medical device:Class A Material of construction:PET tube with Bromo butyl rubber stopper with or without PE safety cap. Dimension(if any): Shelflife:24 months Sterile or Non sterile:Sterilized Brand Name(if registered under the Trade Marks Act, 1999):Vacsure</p>

5	<p>Generic Name:Vacuum Blood Collection Tube-Glucose (Fluoride-K3 EDTA) Tubes Model No.:Vacuum Blood Collection Tube-Glucose (Fluoride-K3 EDTA) Tubes - 1ml, Vacuum Blood Collection Tube-Glucose (Fluoride-K3 EDTA) Tubes - 2ml,Vacuum Blood Collection Tube-Glucose (Fluoride-K3 EDTA) Tubes - 3ml,Vacuum Blood Collection Tube-Glucose (Fluoride-K3 EDTA) Tubes - 4ml,Vacuum Blood Collection Tube-Glucose (Fluoride-K3 EDTA) Tubes - 5ml,Vacuum Blood Collection Tube- Glucose (Fluoride-K3 EDTA) Tubes - 6ml,Vacuum Blood Collection Tube-Glucose (Fluoride-K3 EDTA) Tubes - 7ml,Vacuum Blood Collection Tube-Glucose (Fluoride-K3 EDTA) Tubes - 8ml,Vacuum Blood Collection Tube-Glucose (Fluoride-K3 EDTA) Tubes - 9ml,Vacuum Blood Collection Tube-Glucose (Fluoride-K3 EDTA) Tubes - 10ml</p> <p>Intended Use:For Collection ,storage and transport of blood specimen for diagnostic purpose</p> <p>Class of medical device:Class A</p> <p>Material of construction:PET tube with Bromo butyl rubber stopper with or without PE safety cap.</p> <p>Dimension(if any):</p> <p>Shelflife:24 months</p> <p>Sterile or Non sterile:Sterilized</p> <p>Brand Name(if registered under the Trade Marks Act, 1999):Vacsure</p>
6	<p>Generic Name:Vacuum Blood Collection Tube-Plain Tubes Model No.:Vacuum Blood Collection Tube-Plain Tubes - 1ml,Vacuum Blood Collection Tube-Plain Tubes - 2ml,Vacuum Blood Collection Tube-Plain Tubes - 3ml, Vacuum Blood Collection Tube-Plain Tubes - 4ml,Vacuum Blood Collection Tube-Plain Tubes - 5ml,Vacuum Blood Collection Tube-Plain Tubes - 6ml,Vacuum Blood Collection Tube-Plain Tubes - 7ml,Vacuum Blood Collection Tube-Plain Tubes - 8ml, Vacuum Blood Collection Tube-Plain Tubes - 9ml,Vacuum Blood Collection Tube-Plain Tubes - 10ml</p> <p>Intended Use:For Collection ,storage and transport of blood specimen for diagnostic purpose</p> <p>Class of medical device:Class A</p> <p>Material of construction:PET tube with Bromo butyl rubber stopper with or without PE safety cap.</p> <p>Dimension(if any):</p> <p>Shelflife:24 months</p> <p>Sterile or Non sterile:Sterilized</p> <p>Brand Name(if registered under the Trade Marks Act, 1999):Vacsure</p>
7	<p>Generic Name:Vacuum Blood Collection Tube-Lithium Heparin Tubes Model No.:Vacuum Blood Collection Tube-Lithium Heparin Tubes - 1ml,Vacuum Blood Collection Tube-Lithium Heparin Tubes - 2ml,Vacuum Blood Collection Tube- Lithium Heparin Tubes - 3ml,Vacuum Blood Collection Tube-Lithium Heparin Tubes - 4ml,Vacuum Blood Collection Tube-Lithium Heparin Tubes - 5ml,Vacuum Blood Collection Tube-Lithium Heparin Tubes - 6ml,Vacuum Blood Collection Tube-Lithium Heparin Tubes - 7ml,Vacuum Blood Collection Tube-Lithium Heparin Tubes - 8ml, Vacuum Blood Collection Tube-Lithium Heparin Tubes - 9ml,Vacuum Blood Collection Tube-Lithium Heparin Tubes - 10ml</p> <p>Intended Use:For Collection ,storage and transport of blood specimen for diagnostic purpose</p> <p>Class of medical device:Class A</p> <p>Material of construction:PET tube with Bromo butyl rubber stopper with or without PE safety cap.</p> <p>Dimension(if any):</p> <p>Shelflife:24 months</p> <p>Sterile or Non sterile:Sterilized</p> <p>Brand Name(if registered under the Trade Marks Act, 1999):Vacsure</p>

8	<p>Generic Name:Vacuum Blood Collection Tube-Sodium Heparin Tubes Model No.:Vacuum Blood Collection Tube-Sodium Heparin Tubes - 1ml,Vacuum Blood Collection Tube-Sodium Heparin Tubes - 2ml,Vacuum Blood Collection Tube-Sodium Heparin Tubes - 3ml,Vacuum Blood Collection Tube-Sodium Heparin Tubes - 4ml,Vacuum Blood Collection Tube-Sodium Heparin Tubes - 5ml,Vacuum Blood Collection Tube-Sodium Heparin Tubes - 6ml,Vacuum Blood Collection Tube-Sodium Heparin Tubes - 7ml,Vacuum Blood Collection Tube-Sodium Heparin Tubes - 8ml, Vacuum Blood Collection Tube-Sodium Heparin Tubes - 9ml,Vacuum Blood Collection Tube-Sodium Heparin Tubes - 10ml Intended Use:For Collection ,storage and transport of blood specimen for diagnostic purpose Class of medical device:Class A Material of construction:PET tube with Bromo butyl rubber stopper with or without PE safety cap. Dimension(if any): Shelflife:24 months Sterile or Non sterile:Sterilized Brand Name(if registered under the Trade Marks Act, 1999):Vacsure</p>
9	<p>Generic Name:Vacuum Blood Collection Tube-Clot Activator Tubes Model No.:Vacuum Blood Collection Tube-Clot Activator Tubes - 1ml,Vacuum Blood Collection Tube-Clot Activator Tubes - 2ml,Vacuum Blood Collection Tube-Clot Activator Tubes - 3ml,Vacuum Blood Collection Tube-Clot Activator Tubes - 4ml, Vacuum Blood Collection Tube-Clot Activator Tubes - 5ml,Vacuum Blood Collection Tube-Clot Activator Tubes - 6ml,Vacuum Blood Collection Tube-Clot Activator Tubes - 7ml,Vacuum Blood Collection Tube-Clot Activator Tubes - 8ml,Vacuum Blood Collection Tube-Clot Activator Tubes - 9ml,Vacuum Blood Collection Tube-Clot Activator Tubes - 10ml Intended Use:For Collection ,storage and transport of blood specimen for diagnostic purpose Class of medical device:Class A Material of construction:PET tube with Bromo butyl rubber stopper with or without PE safety cap. Dimension(if any): Shelflife:24 months Sterile or Non sterile:Sterilized Brand Name(if registered under the Trade Marks Act, 1999):Vacsure</p>
10	<p>Generic Name:Vacuum Blood Collection Tube-Clot Activator Tubes + GEL Model No.:Vacuum Blood Collection Tube-Clot Activator Tubes + GEL - 1ml,Vacuum Blood Collection Tube-Clot Activator Tubes + GEL - 2ml,Vacuum Blood Collection Tube-Clot Activator Tubes + GEL - 2.5ml,Vacuum Blood Collection Tube-Clot Activator Tubes + GEL - 3.5ml,,Vacuum Blood Collection Tube-Clot Activator Tubes + GEL - 5ml ,Vacuum Blood Collection Tube-Clot Activator Tubes + GEL - 5.5 ml , Vacuum Blood Collection Tube-Clot Activator Tubes + GEL - 7 ml ,Vacuum Blood Collection Tube-Clot Activator Tubes + GEL - 8.5 ml Intended Use:For Collection ,storage and transport of blood specimen for diagnostic purpose Class of medical device:Class A Material of construction:PET tube with Bromo butyl rubber stopper with or without PE safety cap. Dimension(if any): Shelflife:24 months Sterile or Non sterile:Sterilized Brand Name(if registered under the Trade Marks Act, 1999):Vacsure</p>

11	<p>Generic Name:Vacuum Blood Collection Tube-Sodium Heparin Tubes + GEL Model No.:Vacuum Blood Collection Tube-Sodium Heparin Tubes + GEL - 1ml, Vacuum Blood Collection Tube-Sodium Heparin Tubes + GEL - 2ml,Vacuum Blood Collection Tube-Sodium Heparin Tubes + GEL - 2.5ml,Vacuum Blood Collection Tube-Sodium Heparin Tubes + GEL - 3.5ml,,Vacuum Blood Collection Tube-Sodium Heparin Tubes + GEL - 5ml ,Vacuum Blood Collection Tube-Sodium Heparin Tubes + GEL - 5.5 ml ,Vacuum Blood Collection Tube-Sodium Heparin Tubes + GEL - 7 ml , Vacuum Blood Collection Tube-Sodium Heparin Tubes + GEL - 8.5 ml Intended Use:For Collection ,storage and transport of blood specimen for diagnostic purpose Class of medical device:Class A Material of construction:PET tube with Bromo butyl rubber stopper with or without PE safety cap. Dimension(if any): Shelflife:24 months Sterile or Non sterile:Sterilized Brand Name(if registered under the Trade Marks Act, 1999):Vacsure</p>
12	<p>Generic Name:Vacuum Blood Collection Tube-Lithium Heparin + GEL Model No.:Vacuum Blood Collection Tube-Lithium Heparin + GEL - 1ml,Vacuum Blood Collection Tube-Lithium Heparin + GEL - 2ml,Vacuum Blood Collection Tube- Lithium Heparin + GEL - 2.5ml,Vacuum Blood Collection Tube-Lithium Heparin + GEL - 3.5ml,Vacuum Blood Collection Tube-Lithium Heparin + GEL - 5ml ,Vacuum Blood Collection Tube-Lithium Heparin + GEL - 5.5 ml ,Vacuum Blood Collection Tube-Lithium Heparin + GEL - 7 ml ,Vacuum Blood Collection Tube-Lithium Heparin + GEL - 8.5 ml Intended Use:For Collection ,storage and transport of blood specimen for diagnostic purpose Class of medical device:Class A Material of construction:PET tube with Bromo butyl rubber stopper with or without PE safety cap. Dimension(if any): Shelflife:24 months Sterile or Non sterile:Sterilized Brand Name(if registered under the Trade Marks Act, 1999):Vacsure</p>
13	<p>Generic Name:Vacuum Blood Collection Tube- K3 EDTA + GEL Model No.:Vacuum Blood Collection Tube- K3 EDTA + GEL - 1ml,Vacuum Blood Collection Tube- K3 EDTA + GEL - 2ml,Vacuum Blood Collection Tube- K3 EDTA + GEL - 2.5ml,Vacuum Blood Collection Tube- K3 EDTA + GEL - 3.5ml,Vacuum Blood Collection Tube- K3 EDTA + GEL - 5ml ,Vacuum Blood Collection Tube- K3 EDTA + GEL - 5.5 ml ,Vacuum Blood Collection Tube- K3 EDTA + GEL - 7 ml ,Vacuum Blood Collection Tube- K3 EDTA + GEL - 8.5 ml Intended Use:For Collection ,storage and transport of blood specimen for diagnostic purpose Class of medical device:Class A Material of construction:PET tube with Bromo butyl rubber stopper with or without PE safety cap. Dimension(if any): Shelflife:24 months Sterile or Non sterile:Sterilized Brand Name(if registered under the Trade Marks Act, 1999):Vacsure</p>
14	<p>Generic Name:Vacuum Blood Collection Tube- K2 EDTA + GEL Model No.:Vacuum Blood Collection Tube- K2 EDTA + GEL - 1ml,Vacuum Blood Collection Tube- K2 EDTA + GEL - 2ml,Vacuum Blood Collection Tube- K2 EDTA + GEL - 2.5ml,Vacuum Blood Collection Tube- K2 EDTA + GEL - 3.5ml,,Vacuum Blood Collection Tube- K2 EDTA + GEL - 5ml ,Vacuum Blood Collection Tube- K2 EDTA + GEL - 5.5 ml ,Vacuum Blood Collection Tube- K2 EDTA + GEL - 7 ml ,Vacuum Blood Collection Tube- K2 EDTA + GEL - 8.5 ml Intended Use:For Collection ,storage and transport of blood specimen for diagnostic purpose Class of medical device:Class A Material of construction:PET tube with Bromo butyl rubber stopper with or without PE safety cap. Dimension(if any): Shelflife:24 months Sterile or Non sterile:Sterilized Brand Name(if registered under the Trade Marks Act, 1999):Vacsure</p>

15	<p>Generic Name:Vacuum Blood Collection Tube-Sodium Citrate 3.2% Tubes for coagulation Model No.:Vacuum Blood Collection Tube-Sodium Citrate 3.2 percentage Tubes for coagulation - 1.8 ml ,Vacuum Blood Collection Tube-Sodium Citrate 3.2 percentage Tubes for coagulation - 2.7 ml ,Vacuum Blood Collection Tube-Sodium Citrate 3.2 percentage Tubes for coagulation - 3.6 ml,Vacuum Blood Collection Tube-Sodium Citrate 3.2 percentage Tubes for coagulation - 4.5 ml ,Vacuum Blood Collection Tube-Sodium Citrate 3.2 percentage Tubes for coagulation - 5.4 ml,Vacuum Blood Collection Tube-Sodium Citrate 3.2 percentage Tubes for coagulation - 6.3 ml, Vacuum Blood Collection Tube-Sodium Citrate 3.2 percentage Tubes for coagulation - 7.2 ml,Vacuum Blood Collection Tube-Sodium Citrate 3.2 percentage Tubes for coagulation - 8.1 ml,Vacuum Blood Collection Tube-Sodium Citrate 3.2 percentage Tubes for coagulation - 9 ml Intended Use:For Collection ,storage and transport of blood specimen for diagnostic purpose Class of medical device:Class A Material of construction:PET tube with Bromo butyl rubber stopper with or without PE safety cap. Dimension(if any): Shelflife:15 months Sterile or Non sterile:Sterilized Brand Name(if registered under the Trade Marks Act, 1999):Vacsure</p>
16	<p>Generic Name:Vacuum Blood Collection Tube-Sodium Citrate 3.8% (ESR) Tubes Model No.:Vacuum Blood Collection Tube-Sodium Citrate 3.8 percentage(ESR) Tubes - 1.6 ml,Vacuum Blood Collection Tube-Sodium Citrate 3.8 percentage(ESR) Tubes - 2.4 ml ,Vacuum Blood Collection Tube-Sodium Citrate 3.8 percentage(ESR) Tubes - 3.2 ml Intended Use:For Collection ,storage and transport of blood specimen for diagnostic purpose Class of medical device:Class A Material of construction:PET tube with Bromo butyl rubber stopper with or without PE safety cap. Dimension(if any): Shelflife:15 months Sterile or Non sterile:Sterilized Brand Name(if registered under the Trade Marks Act, 1999):Vacsure</p>
17	<p>Generic Name:Vacuum Blood Collection Tube- Automated ESR Tubes (Sodium Citrate 3.8%) Model No.:Vacuum Blood Collection Tube- Automated ESR Tubes (Sodium Citrate 3.8 percentage) - 1.28 ml Intended Use:For Collection ,storage and transport of blood specimen for diagnostic purpose Class of medical device:Class A Material of construction:PET tube with Bromo butyl rubber stopper with or without PE safety cap. Dimension(if any): Shelflife:15 months Sterile or Non sterile:Sterilized Brand Name(if registered under the Trade Marks Act, 1999):Vacsure</p>
18	<p>Generic Name:Vacuum Blood Collection Tube-Acid Citrate Dextrose (ACD)-A Tubes Model No.:Vacuum Blood Collection Tube-Acid Citrate Dextrose (ACD)-A Tubes - 8.5 ml Intended Use:For Collection ,storage and transport of blood specimen for diagnostic purpose Class of medical device:Class A Material of construction:PET tube with Bromo butyl rubber stopper with or without PE safety cap. Dimension(if any): Shelflife:15 months Sterile or Non sterile:Sterilized Brand Name(if registered under the Trade Marks Act, 1999):Vacsure</p>

19	<p>Generic Name:Vacuum Blood Collection Tube-Acid Citrate Dextrose (ACD)- B Tubes Model No.:Vacuum Blood Collection Tube-Acid Citrate Dextrose (ACD)- B Tubes - 6 ml Intended Use:For Collection ,storage and transport of blood specimen for diagnostic purpose Class of medical device:Class A Material of construction:PET tube with Bromo butyl rubber stopper with or without PE safety cap. Dimension(if any): Shelflife:15 months Sterile or Non sterile:Sterilized Brand Name(if registered under the Trade Marks Act, 1999):Vacsure</p>
20	<p>Generic Name:Vacuum Blood Collection Tubes-Acid Citrate Dextrose (ACD) + Gel Tubes Model No.:Vacuum Blood Collection Tubes-Acid Citrate Dextrose (ACD) + Gel Tubes - 7.5 ml Intended Use:For Collection ,storage and transport of blood specimen for diagnostic purpose Class of medical device:Class A Material of construction:PET tube with Bromo butyl rubber stopper with or without PE safety cap. Dimension(if any): Shelflife:15 months Sterile or Non sterile:Sterilized Brand Name(if registered under the Trade Marks Act, 1999):Vacsure</p>
21	<p>Generic Name:Vacuum Blood Collection Tube-Sodium Citrate 3.2% + Gel Tubes Model No.:Vacuum Blood Collection Tube-Sodium Citrate 3.2 percentage + Gel Tubes - 2.8 ml,Vacuum Blood Collection Tube-Sodium Citrate 3.2 percentage + Gel Tubes - 3.7 ml,Vacuum Blood Collection Tube-Sodium Citrate 3.2 percentage + Gel Tubes - 4.6 ml,Vacuum Blood Collection Tube-Sodium Citrate 3.2 percentage + Gel Tubes - 7.8 ml Intended Use:For Collection ,storage and transport of blood specimen for diagnostic purpose Class of medical device:Class A Material of construction:PET tube with Bromo butyl rubber stopper with or without PE safety cap. Dimension(if any): Shelflife:15 months Sterile or Non sterile:Sterilized Brand Name(if registered under the Trade Marks Act, 1999):Vacsure</p>

Place:

Date28-Sep-22

State Licensing Authority