

प्रेषक,

औषधि अनुज्ञापन एवं नियंत्रण प्राधिकारी
कार्यालय आयुक्त, खाद्य सुरक्षा एवं औषधि प्रशासन, उ.प्र.
सेक्टर – सी, अलीगंज, लखनऊ, उ.प्र.

सेवा में,

M/S Care Medical Devices Ltd
D-1/3B, Sector-13, GIDA, Gorakhpur-273209 (U.P.)
Uttar Pradesh (India) - 273209

फाइल संख्या - MFG/MD/2020/17968

लखनऊ, दिनांक : 10-12-2020

विषय: प्रपत्र एमडी-5 पर मेडिकल डिवाइस निर्माण अनुमति प्रदान किये जाने के सम्बन्ध में।

महोदय,

उपर्युक्त विषयक आपके ऑनलाइन आवेदन पत्र पर विचारोपरान्त फार्म एमडी-5 पर मेडिकल डिवाइस निर्माण हेतु नवीन लासेंस संख्या- MFG/MD/2020/000308 दिनांक- 10-12-2020, मेडिकल डिवाइस रूल्स, 2017 में निहित प्राविधानों एवं औषधि एवं प्रसाधन सामग्री अधिनियम, 1940 के अधीन स्वीकृत कर प्रेषित किया जा रहा है।

अनुज्ञापी द्वारा औषधि एवं प्रसाधन सामग्री अधिनियम, 1940 एवं तत्सम्बन्धी नियमावली के प्राविधानों तथा समय-समय पर सक्षम प्राधिकारी द्वारा निर्गत निर्देशों का अनुपालन किया जायेगा।

संलग्नक – उपरोक्तानुसार।

भवदीय

(ए. के. जैन)

औषधि अनुज्ञापन एवं नियंत्रण प्राधिकारी,
उत्तर प्रदेश

फाइल संख्या - MFG/MD/2020/17968

तद्दिनांक

प्रतिलिपि निम्नलिखित के सूचनार्थ एवं आवश्यक कार्यवाही हेतु प्रेषित –

1. सहायक आयुक्त (औषधि), खाद्य सुरक्षा एवं औषधि प्रशासन, कार्यालय मण्डलायुक्त, Gorakhpur मण्डल
2. औषधि निरीक्षक, खाद्य सुरक्षा एवं औषधि प्रशासन, कार्यालय जिलाधिकारी, Gorakhpur

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(ए. के. जैन)

औषधि अनुज्ञापन एवं नियंत्रण प्राधिकारी,
उत्तर प्रदेश



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/2020/000308

1. M/s Care Medical Devices Ltd, D-1/3B, Sector-13, GIDA, Gorakhpur-273209 U.P.GIDA, --, Uttar Pradesh (India) - 273209 Telephone No.: 9918060809 FAX: 5512201022 has been licenced to manufacture for sale or for distribution the below listed medical device(s) at the premises situated at M/s Care Medical Devices Ltd, D-1/3B, Sector-13, GIDA, Gorakhpur-273209 (U.P.) INDIA, Gorakhpur, Uttar Pradesh (India) - 273209 Telephone No.: 9918060809 FAX: 551-2201022

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: Blood Transfusion Set Model No.: - , - , - , - , - , - , - , - , Vented / Non Vented blood transfusion set with latex bulb Luer Slip with 18G needle. - no , Vented / Non Vented blood transfusion Set with Y Site Luer lock with Needle 18G - no , Blood transfusion set with Airvent with Y Site with Needle 18G. - no , Single / Double chamber with / without Airway. - no , - , - Intended Use: Blood transfusion set is used in delivering measured and regulated blood to patient. Blood Transfusion Set is made of cylindrical drip chamber with / without vent provided with filter for use with blood bag or blood bottle respectively. It has efficient roller controller for accurate adjustment of Transfusion rate and has latex flush valve ball for extra medication. Class of medical device: Class B Material of construction: LDPE , ABS, PVC SOFT (DEHP FREE), LATEX RUBBER (LR), PP, NYLON Dimension(if any): 150 cm Shelflife: 3 YEAR Sterile or Non sterile: Sterilized Brand Name(if registered under the Trade Marks Act, 1999): CARE

2	Generic Name:IV CANNULA Model No.:I.V. Cannula with wings with port - no ,I.V. Cannula with wings without port - no ,I.V. Cannula without wings without port - no Intended Use:IV Cannula is used as a medical device on the patient who is required to be administered intravenous medicines frequently Class of medical device:Class B Material of construction:PTFE/ FEP, Polypropylene, Polythene, Stainless steel, Polyacetal Dimension(if any):14G, 16G, 17G, 18G, 20G, 22G, 24G, 26G Shelflife:3 YEAR Sterile or Non sterile:Sterilized Brand Name(if registered under the Trade Marks Act, 1999):CARE
3	Generic Name:Intravenous Infusion Set Model No.: - , - ,with Air-Inlet device - no ,Intravenous Infusion Set with Air Vent /with or without flow regulator - no ,Intravenous Infusion Set without Air Vent /with or without flow regulator - no ,Micro Drip infusion set - no Intended Use:The Infusion Sets are used to administer Intravenous fluid and medicines into human circulating system by using intravenous catheter or cannulae. Class of medical device:Class B Material of construction:LDPE ,ABS, PVC SOFT (DEHP FREE), NATURAL RUBBER,PP, NYLON Dimension(if any):1450 mm Shelflife:3 year Sterile or Non sterile:Sterilized Brand Name(if registered under the Trade Marks Act, 1999):CARE
4	Generic Name:Measured volume Infusion sets Model No.:Measured Volume Set with Flow Regulator with or without y site Luer lock Needle - no ,Measured Volume set Without Flow Regulator with or without y site Luer lock needle - no Intended Use:Measured volume Infusion sets are single use, sterile devices with a cylindrical graduated container called burette used to administer measured volume of intravenous fluids/liquids and/or drugs/medicine into human circulatory system. The burette is used to prepare cocktails of drugs and physiological liquids for infusion. It can also be used for enteral or parenteral feedings especially in pediatric ward. It is used in between containers of infusion solution & intravenous equipment. Class of medical device:Class B Material of construction:LDPE, ABS, PVC SOFT(DEHP FREE), NATURAL RUBBER, PP, FILTER PAPER, LATEX RUBBER, PETG , SS, NYLON, Dimension(if any):100 ml , 110 ml & 150 ml Shelflife:3 YEAR Sterile or Non sterile:Sterilized Brand Name(if registered under the Trade Marks Act, 1999):CARE
5	Generic Name:Hypodermic Syringe Model No.:INSULIN - no ,AD SYRINGE - no ,WITH NEEDLE OR WITH OUT NEEDLE - no Intended Use:Syringe: This device is used for infusing into human body through a needle which is mounted externally on the cone tip. This device is used to infuse medicine or to draw blood from the human body for testing. Class of medical device:Class B Material of construction:PP ,TPE , Black Ink, Silicon, Hexane, Epoxy, SS Cannula, Iron Roller, Dimension(if any):1ml , 2ml , 3ml , 5ml , 10ml , 20ml ,50ml , Shelflife:3 YEAR Sterile or Non sterile:Sterilized Brand Name(if registered under the Trade Marks Act, 1999):CARE

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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/2020/000308

Endorsement No. 1

1. M/s Care Medical Devices Ltd, D-1/3B, Sector-13, GIDA, Gorakhpur-273209 U.P.GIDA, --, Uttar Pradesh (India) - 273209 Telephone No.: 9918060809 FAX: 5512201022 has been licenced to manufacture for sale or for distribution the below listed medical device(s) at the premises situated at M/s Care Medical Devices Ltd, D-1/3B, Sector-13, GIDA, Gorakhpur-273209 (U.P.) INDIA, Gorakhpur, Uttar Pradesh (India) - 273209 Telephone No.: 9918060809 FAX: 551-2201022

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:0.5ml Hypodermic Syringe Model No.:Syringe - With Needle,Syringe - With Out Needle Intended Use:Syringe: This device is used for infusing into human body through a needle which is mounted externally on the cone tip. This device is used to infuse medicine or to draw blood from the human body for testing. Class of medical device:Class B Material of construction:PP, TPE, Black Ink, Silicon, Hexane, Epoxy, SS Cannula, Iron Roller Dimension(if any):0.5ml Syringe Shelflife:3 Years Sterile or Non sterile:Sterilized Brand Name(if registered under the Trade Marks Act, 1999):CARE

Place:

Date:17-Sep-21

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State Licensing Authority

Drug Licensing and Controlling Authority
Uttar Pradesh



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/2020/000308

Endorsement No. 2

1. M/s Care Medical Devices Ltd, D-1/3B, Sector-13, GIDA, Gorakhpur-273209 U.P.GIDA, --, Uttar Pradesh (India) - 273209 Telephone No.: 9918060809 FAX: 5512201022 has been licenced to manufacture for sale or for distribution the below listed medical device(s) at the premises situated at M/s Care Medical Devices Ltd, D-1/3B, Sector-13, GIDA, Gorakhpur-273209 (U.P.) INDIA, Gorakhpur, Uttar Pradesh (India) - 273209 Telephone No.: 9918060809 FAX: 551-2201022

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:AD Syringe (Syringe with reuse prevention feature) Model No.:Ad Syringe - With Needle ,Ad Syringe - Without Needle Intended Use:This device is used for infusing into human body through a needle which is mounted externally on the cone tip. This device is used to infuse medicine or to draw blood from the human body for testing Class of medical device:Class B Material of construction:Polypropylene (PP), Thermo plastic Elastomer(TPE), Black Ink, Silicon, Hexane, Epoxy, Stainless Steel Needle, Iron Roller, Rubber Roller, Laminate, Paper Tape, Ethylene oxide Gas (ETO Gas) Dimension(if any):0.5ml, 1ml, 2 ml 3ml 5ml. 10ml, 20ml, 50ml Shelflife:3 Years Sterile or Non sterile:Sterilized Brand Name(if registered under the Trade Marks Act, 1999):Care

2	Generic Name:Insulin Syringe Model No.:40Unit & 100 Units - In House Intended Use:Insulin Syringe- Solely for the subcutaneous single-use injection of insulin only in humans with which the syringes are filled by the end user and used immediately after filling. Syringes are not intended to contain insulin for extended periods of time. Class of medical device:Class B Material of construction:Polypropylene (PP), Thermo plastic Elastomer(TPE), Master Batch , Black Ink, Silicon, Hexane, Epoxy, Stainless Steel Needle, Iron Roller, Rubber Roller, Laminate, Paper Tape, Ethylene oxide Gas (ETO Gas) Dimension(if any):40Unit & 100 Unit Shelflife:3 Years Sterile or Non sterile:Sterilized Brand Name(if registered under the Trade Marks Act, 1999):Care
3	Generic Name:Single Lumen Hypodermic Needle Model No.:NIL Intended Use:Needle: A hypodermic needle single used for infusing into human body through a syringe which is mounted externally on the cone tip. This device is used to infuse medicine or to draw blood from the human body for testing. Lumen needle is device intended to inject fluids into, or withdraw fluids from, parts of body below the surface of skin Class of medical device:Class B Material of construction:Polypropylene (PP), Pigment, Silicon, Hexane, Epoxy, Stainless Steel Cannula, Ethylene oxide Gas (ETO Gas) Dimension(if any):16G, 18G, 19G, 20G, 22G, 23G, 24G, 25G, 26G Shelflife:3 Years Sterile or Non sterile:Sterilized Brand Name(if registered under the Trade Marks Act, 1999):Care

Place: Lucknow

Date:07-Jul-22

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Drug Licensing and Controlling Authority
Uttar Pradesh
State Licensing Authority