



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/2023/000528

1. M/s SEGURO LIFESCIENCES, PLOT 2(i)A EPIP PHASE 1 JHARMAJARI BADDI BADDI, Solan-BBN, Himachal Pradesh (India) - 174205 Telephone No.: 9816015678 FAX: 9816011985 has been licenced to manufacture for sale or for distribution the below listed medical device(s) at the premises situated at M/s Seguro Lifesciences, PLOT 2(i)A EPIP PHASE 1, JHARMAJARI, BADDI, Solan-BBN, Himachal Pradesh (India) - 173205 Telephone No.: 9816015678 FAX: 9816015678

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:Control Device</p> <p>Model No.:SLS/SCD/700101 - Control Device (2 / 3 / 5 / 10 / 12 / 20ml)</p> <p>Intended Use:Control Device is precisely designed for use during PTCA and other intravascular therapeutic procedures that need to inject die or any other fluid material</p> <p>Class of medical device:Class A</p> <p>Material of construction:Polycarbonate (PC), Acrylonitrile butadiene styrene (ABS) and Silicon</p> <p>Dimension(if any):</p> <p>Shelflife:3 Years</p> <p>Sterile or Non sterile:Sterilized</p> <p>Brand Name(if registered under the Trade Marks Act, 1999):SEGURO/ULTIMA/MAGNA</p>
2	<p>Generic Name:Torque Device</p> <p>Model No.:SLS/STD/900101 - Torque Device up to 0.014 (in)</p> <p>Intended Use:Torque Device is design to facilitate steering of 0.010" to 0.014" guide wires inside the vasculature.</p> <p>Class of medical device:Class A</p> <p>Material of construction:Acrylonitrile butadiene styrene (ABS) and Brass</p> <p>Dimension(if any):</p> <p>Shelflife:3 Years</p> <p>Sterile or Non sterile:Sterilized</p> <p>Brand Name(if registered under the Trade Marks Act, 1999):SEGURO/ULTIMA/MAGNA</p>

3	<p>Generic Name:Femo Seal Pad</p> <p>Model No.:SLS/FSP/130101 - Femo seal Pad</p> <p>Intended Use:This product is an auxiliary device used for the compression of Femoral artery after Trans Femoral interventional procedure. The device is also indicated in the reduction of active compression time in femoral artery cannulation following diagnostic and interventional procedures.</p> <p>Class of medical device:Class A</p> <p>Material of construction:PU and PVC</p> <p>Dimension(if any):</p> <p>Shelflife:3 Years</p> <p>Sterile or Non sterile:Sterilized</p> <p>Brand Name(if registered under the Trade Marks Act, 1999):SEGURO/ULTIMA/MAGNA</p>
4	<p>Generic Name:Trans Radial/Femoral Compression Device</p> <p>Model No.:SLS/RCD/100101 - Trans Radial Compression Device Small (24cm wrist band), SLS/RCD/100102 - Trans Radial Compression Device Large (28cm wrist band), SLS/FCD/100103 - Femoral Compression Device</p> <p>Intended Use:Trans Radial compression device is an auxiliary device used for the compression of radial artery after Trans radial interventional procedure. Trans femoral compression device is pressure assisted devices are to assist for maintaining Hemostasis. The device is also indicated in the reduction of active compression time in femoral artery cannulation following diagnostic and interventional procedures</p> <p>Class of medical device:Class A</p> <p>Material of construction:PVC, PU and PC</p> <p>Dimension(if any):</p> <p>Shelflife:3 Years</p> <p>Sterile or Non sterile:Sterilized</p> <p>Brand Name(if registered under the Trade Marks Act, 1999):SEGURO/ULTIMA/MAGNA</p>
5	<p>Generic Name:Introducer Needle</p> <p>Model No.:SLS/ING/800101 - Guide Wire Introducer Needle 18G ,SLS/ING/800102 - Guide Wire Introducer Needle 20G ,SLS/ING/800103 - Guide Wire Introducer Needle 21G</p> <p>Intended Use:Introducer Needle is an accessory to puncture the femoral artery for introducing the Guide wire within the body during Angioplasty. Introducer Needle is precisely designed for use during Percutaneous Trans luminal Coronary Angioplasty (PTCA) and any other intravascular therapeutic procedures that utilize a guiding catheter.</p> <p>Class of medical device:Class B</p> <p>Material of construction:Stainless Steel 304 Medical Grade, poly carbonate</p> <p>Dimension(if any):</p> <p>Shelflife:3 Years</p> <p>Sterile or Non sterile:Sterilized</p> <p>Brand Name(if registered under the Trade Marks Act, 1999):SEGURO/ULTIMA/MAGNA</p>

6	<p>Generic Name:Manifold</p> <p>Model No.:SLS/MTP/400101 - 2 Port Manifold Right (Off),SLS/MTP/400102 - 2 Port Manifold Right (On),SLS/MTP/400103 - 3 Port Manifold Right (Off),SLS/MTP/400104 - 3 Port Manifold Right (On)</p> <p>Intended Use:Manifold is indicated for fluid flow directional control and for providing access ports for administration of solutions. Typical uses include pressure monitoring, intravenous fluid administration and transfusion.</p> <p>Class of medical device:Class B</p> <p>Material of construction:Polycarbonate (PC) and Acrylonitrile Butadiene Styrene (ABS)</p> <p>Dimension(if any):</p> <p>Shelflife:3 Years</p> <p>Sterile or Non sterile:Sterilized</p> <p>Brand Name(if registered under the Trade Marks Act, 1999):SEGURO/ULTIMA/MAGNA</p>
7	<p>Generic Name:Pressure Monitoring Line</p> <p>Model No.:SLS/PML/500101 - Seguro Pressure Monitoring Line 25cm,SLS/PML/500102 - Seguro Pressure Monitoring Line 50cm,SLS/PML/500103 - Seguro Pressure Monitoring Line 100cm,SLS/PML/500104 - Seguro Pressure Monitoring Line 150cm,SLS/PML/500105 - Seguro Pressure Monitoring Line 120cm,SLS/PML/500106 - Seguro Pressure Monitoring Line 200cm,SLS/PML/500107 - Seguro Pressure Monitoring Line 250 cm,SLS/PML/500108 - Seguro Pressure Monitoring Line 300cm,SLS/HPL/600101 - Seguro High Pressure Monitoring Line 25cm,SLS/HPL/600102 - Seguro High Pressure Monitoring Line 50cm,SLS/HPL/600103 - Seguro High Pressure Monitoring Line 75cm,SLS/HPL/600104 - Seguro High Pressure Monitoring Line 100cm,SLS/HPL/600105 - Seguro High Pressure Monitoring Line 120cm, SLS/HPL/600106 - Seguro High Pressure Monitoring Line 150cm</p> <p>Intended Use:Pressure Monitoring Line is precisely designed for use during PTCA and any other intravascular therapeutic procedures that need to monitor pressure of any fluid or blood.</p> <p>Class of medical device:Class B</p> <p>Material of construction:Polyvinylchloride (PVC) and Polycarbonate (PC)</p> <p>Dimension(if any):</p> <p>Shelflife:3 Years</p> <p>Sterile or Non sterile:Sterilized</p> <p>Brand Name(if registered under the Trade Marks Act, 1999):SEGURO/ULTIMA/MAGNA</p>

8	<p>Generic Name:Hemostatis Y Connector with Torquer and Blunt Introducer</p> <p>Model No.:SLS/YSC/300101 - Hemostasis Y Connector (Screw Type),SLS/YPP/300102 - Hemostasis Y Connector (Push pull with side arm stopcock),SLS/YPC/300103 - Hemostasis Y Connector (Push Click with side arm stopcock),SLS/YPP/300104 - Hemostasis Y Connector Kit (Push pull with side arm stopcock, Blunt introducer & Torquer),SLS/YPC/300105 - Hemostasis Y Connector Kit (Push Click with side arm stopcock Blunt introducer & Torquer)</p> <p>Intended Use:Y CONNECOTR: Y-Connector: (Push Click Type, Push Pull Type, Screw Type), Y Connector intends to provide two tunnels into the blood vessel; this can introduce the contrast medium and guide wire or catheters during the interventional surgery. Y Connector valve intends to prevent blood lost. It provides a mean for inserting guide wires or catheters deep into the vasculature, and positioning and locking them into a desired place. Y-connector includes a straight and a side access lumen. The hemostasis valve located at the proximal end of the straight lumen can be opened or closed by operation of the Push-click button. The distal end has a rotating male luer lock. The side access lumen allows pressure monitoring and perfusion. Blunt Introducer (Insertion Tool): It is an accessory design to facilitate the introduction of guide wires (up to 0.018") used in conjunction with interventional devices during vascular interventional procedures. Blunt introducer inserts the valve of Y connector, making a tunnel for guide wire to get through and protecting guide wire tip. Torquer: Torquer holds guide wire and makes torque guide wire move easily. It is design to facilitate steering of 0.010" to 0.014" guide wires inside the vasculature.</p> <p>Class of medical device:Class B</p> <p>Material of construction:Polycarbonate (PC), Polyvinylchloride (PVC), Silicon, Acrylonitrile butadiene styrene (ABS), Brass, Stainless Steel 304</p> <p>Dimension(if any):</p> <p>Shelflife:3 Years</p> <p>Sterile or Non sterile:Sterilized</p> <p>Brand Name(if registered under the Trade Marks Act, 1999):SEGURO/ULTIMA/MAGNA</p>
9	<p>Generic Name:Balloon Inflation Device</p> <p>Model No.:SLS/BGT/200101 - Balloon Inflation Device (Gun Type) GT,SLS/BRT/200102 - Balloon Inflation Device (Mega Type) RT,SLS/BMT/200103 - Balloon Inflation Device (Ultima Type) UT</p> <p>Intended Use:Balloon inflation device is precisely designed for use during PTCA and any other intravascular therapeutic procedures that utilize a balloon catheter and pressure monitoring.</p> <p>Class of medical device:Class B</p> <p>Material of construction:Polycarbonate, Silicone</p> <p>Dimension(if any):</p> <p>Shelflife:3 Years</p> <p>Sterile or Non sterile:Sterilized</p> <p>Brand Name(if registered under the Trade Marks Act, 1999):SEGURO/ULTIMA/MAGNA</p>
10	<p>Generic Name:Angiodye Connector</p> <p>Model No.:SLS/ADC/100101 - Angio Dye Connector</p> <p>Intended Use:Angio Dye Connector is precisely designed for use during PTCA and other intravascular therapeutic procedures that need to inject die or any other fluid material.</p> <p>Class of medical device:Class B</p> <p>Material of construction:Polycarbonate (PC), Polyvinylchloride (PVC).</p> <p>Dimension(if any):</p> <p>Shelflife:3 Years</p> <p>Sterile or Non sterile:Sterilized</p> <p>Brand Name(if registered under the Trade Marks Act, 1999):SEGURO/ULTIMA/MAGNA</p>

Place:

Date 24-May-23

State Licensing Authority

24/5/23

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