

F NO :

Government of India
Directorate General of Health Services
Central Drugs Standard Control Organisation
Ministry of Health and Family welfare
(Medical Device and Diagnostic Division)

FREE SALE CERTIFICATE

FSC Number : FSC/MD/2024/000124

Dated : 21/02/2024

This is to certify that M/s. SEGURO LIFESCIENCES, Seguro Lifesciences situated at address PLOT 2(i)A EPIP PHASE 1, JHARMAJARI, BADDI, Solan-BBN Himachal Pradesh, 173205, 9816015678, India is holding Manufacturing License no. MFG/MD/2023/000528 issued on 24-MAY-2023 Under this license, the said firm is permitted to manufacture the products for their manufacture and sale in domestic market as per Indian Law and for export as per law of importing country (ies):-

Name of the products with their product name and dimensions if any mentioned below :

S.NO	Medical Device Details
1	1. Generic Name :Control Device 2. Brand Name :SEGURO/ULTIMA/MAGNA 3. Notified Category :Disposable Hypodermic Syringes 4. Class of Medical Device :Class A 5. Shelf life :3 Years 6. Sterile/Non-Sterile: Sterilized 7. 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 8. Material of Construction: Polycarbonate (PC), Acrylonitrile butadiene styrene (ABS) and Silicon 9. Dimension: NA 10. Model/Catalogue No./Name :SLS/SCD/700101 - Control Device (2 / 3 / 5 / 10 / 12 / 20ml)
2	1. Generic Name :Torque Device 2. Brand Name :SEGURO/ULTIMA/MAGNA 3. Notified Category :Catheters 4. Class of Medical Device :Class A 5. Shelf life :3 Years 6. Sterile/Non-Sterile: Sterilized 7. Intended Use :Torque Device is design to facilitate steering of 0.010" to 0.014" guide wires inside the vasculature. 8. Material of Construction: Acrylonitrile butadiene styrene (ABS) and Brass 9. Dimension: NA 10. Model/Catalogue No./Name :SLS/STD/900101 - Torque Device up to 0.014 (in)

3	1. Generic Name :Femo Seal Pad 2. Brand Name :SEGURO/ULTIMA/MAGNA 3. Notified Category :Disposable Perfusion Sets 4. Class of Medical Device :Class A 5. Shelf life :3 Years 6. Sterile/Non-Sterile: Sterilized 7. 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. 8. Material of Construction: PU and PVC 9. Dimension: NA 10. Model/Catalogue No./Name :SLS/FSP/130101 - Femo seal Pad
4	1. Generic Name :Trans Radial/Femoral Compression Device 2. Brand Name :SEGURO/ULTIMA/MAGNA 3. Notified Category :Disposable Perfusion Sets 4. Class of Medical Device :Class A 5. Shelf life :3 Years 6. Sterile/Non-Sterile: Sterilized 7. 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 8. Material of Construction: PVC, PU and PC 9. Dimension: NA 10. Model/Catalogue No./Name :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
5	1. Generic Name :Introducer Needle 2. Brand Name :SEGURO/ULTIMA/MAGNA 3. Notified Category :Disposable Hypodermic Needles 4. Class of Medical Device :Class B 5. Shelf life :3 Years 6. Sterile/Non-Sterile: Sterilized 7. 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. 8. Material of Construction: Stainless Steel 304 Medical Grade, poly carbonate 9. Dimension: NA 10. Model/Catalogue No./Name :SLS/ING/800101 - Guide Wire Introducer Needle 18G, SLS/ING/800102 - Guide Wire Introducer Needle 20G, SLS/ING/800103 - Guide Wire Introducer Needle 21G
6	1. Generic Name :Manifold 2. Brand Name :SEGURO/ULTIMA/MAGNA 3. Notified Category :Disposable Perfusion Sets 4. Class of Medical Device :Class B 5. Shelf life :3 Years 6. Sterile/Non-Sterile: Sterilized 7. 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. 8. Material of Construction: Polycarbonate (PC) and Acrylonitrile Butadiene Styrene (ABS) 9. Dimension: NA 10. Model/Catalogue No./Name :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)

7	1. Generic Name :Pressure Monitoring Line 2. Brand Name :SEGURO/ULTIMA/MAGNA 3. Notified Category :Catheters 4. Class of Medical Device :Class B 5. Shelf life :3 Years 6. Sterile/Non-Sterile: Sterilized 7. 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. 8. Material of Construction: Polyvinylchloride (PVC) and Polycarbonate (PC) 9. Dimension: NA 10. Model/Catalogue No./Name :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
8	1. Generic Name :Hemostatis Y Connector with Torquer and Blunt Introducer 2. Brand Name :SEGURO/ULTIMA/MAGNA 3. Notified Category :Catheters 4. Class of Medical Device :Class B 5. Shelf life :3 Years 6. Sterile/Non-Sterile: Sterilized 7. 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. 8. Material of Construction: Polycarbonate (PC), Polyvinylchloride (PVC), Silicon, Acrylonitrile butadiene styrene (ABS), Brass, Stainless Steel 304 9. Dimension: NA 10. Model/Catalogue No./Name :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)
9	1. Generic Name :Balloon Inflation Device 2. Brand Name :SEGURO/ULTIMA/MAGNA 3. Notified Category :Others Cardiovascular Intervention Devices 4. Class of Medical Device :Class B 5. Shelf life :3 Years 6. Sterile/Non-Sterile: Sterilized 7. 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. 8. Material of Construction: Polycarbonate, Silicone 9. Dimension: NA 10. Model/Catalogue No./Name :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

10	1. Generic Name :Angiodye Connector 2. Brand Name :SEGURO/ULTIMA/MAGNA 3. Notified Category :Catheters 4. Class of Medical Device :Class B 5. Shelf life :3 Years 6. Sterile/Non-Sterile: Sterilized 7. Intended Use :Angio Dye Connector is precisely designed for use during PTCA and other intravascular therapeutic procedures that need to inject dye or any other fluid material. 8. Material of Construction: Polycarbonate (PC), Polyvinylchloride (PVC). 9. Dimension: NA 10. Model/Catalogue No./Name :SLS/ADC/100101 - Angio Dye Connector
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