

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/2024/000623**

Dated : 22/10/2024

This is to certify that M/s. **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/2023/001015** issued on **01-DEC-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 :Surgical Suture 2. Brand Name :SEGURO/ULTIMA/MAGNA 3. Notified Category :Sutures 4. Class of Medical Device :Class C 5. Shelf life :3 Years 6. Sterile/Non-Sterile:Sterilized 7. Intended Use :Suture is indicated for use in general soft tissue approximation and/or ligation including cardiovascular surgery, neurosurgery and ophthalmic procedures including microsurgery. 8. Material of Construction: Thread of silkworm and Thread of Nylon, Stainless Steel 304 Medical Grade 9. Dimension: 1 (Metric 4) (0.400-0.499), 2 (Metric 5) (0.500-0.599), 3 (Metric 6) (0.600-0.699), 1-0 (Metric 3.5) (0.350-0.399), 2-0 (Metric 3) (0.300-0.399), 3-0 (Metric 2) (0.200-0.299), 4-0 (Metric 1.5) (0.150-0.199), 20 (USP 1) (0.500-0.599), 30 (USP 2/0) (0.400-0.499), 40 (USP 3/0) (0.300-0.399), 60 (USP 3) (0.200-0.299), 80 (USP 4/0) (0.150-0.199), 100 (USP 5/0) (0.100-0.120) 10. Model/Catalogue No./Name :SLS/STR/110101 - 1 (Metric 4) ,SLS/STR/110102 - 2 (Metric 5) ,SLS/STR/110103 - 3 (Metric 6) ,SLS/STR/110104 - 1-0 (Metric 3.5) , SLS/STR/110105 - 2-0 (Metric 3) ,SLS/STR/110106 - 3-0 (Metric 2) ,SLS/STR/110107 - 4-0 (Metric 1.5) ,SLS/STR/110108 - 20 (USP 1) ,SLS/STR/110109 - 30 (USP 2/0) ,SLS/STR/110110 - 40 (USP 3/0) ,SLS/STR/110111 - 60 (USP 3) ,SLS/STR/110112 - 80 (USP 4/0) ,SLS/STR/110113 - 100 (USP 5/0)

2	1. Generic Name :PTCA Balloon Catheter 2. Brand Name :SEGURO/ULTIMA/MAGNA 3. Notified Category :Catheters 4. Class of Medical Device :Class C 5. Shelf life :3 Years 6. Sterile/Non-Sterile:Sterilized 7. Intended Use :The PTCA Balloon catheter is intended for balloon dilatation of the stenotic portion of a coronary artery or bypass graft stenosis for the purpose of improving myocardial perfusion. 8. Material of Construction: Stainless Steel 304medical grade, Polycarbonate (PC), Nylons 9. Dimension: Balloon length (9 mm to 41 mm), Vessel size (2.5 mm to 4.0 mm), Rapid Exchange Length (250 ± 20 mm), Catheter Length (1400 ± 50 mm), Distance between two ring markers (Balloon working length – 0.5 mm Tolerance ± 0.5 mm), Proximal Shaft Dia. (greater than or equal to 0.64 mm), Distal Shaft Dia. (greater than or equal to 0.87mm), Tip lead-in Dia. (less than 0.57 ± 0.3 mm), Balloon Tip length (4.0 ± 1.0 mm), Protection Wire outer Dia. (0.39 mm ± 0.01mm) 10. Model/Catalogue No./Name :SLS/BLN/120101 - PTCA Balloon Catheter
3	1. Generic Name :Introducer Radial/Femoral Sheath 2. Brand Name :SEGURO/ULTIMA/MAGNA 3. Notified Category :Catheters 4. Class of Medical Device :Class C 5. Shelf life :3 Years 6. Sterile/Non-Sterile:Sterilized 7. Intended Use :Introducer Sheath is intended to provide access and facilitate the percutaneous introduction of various devices into veins and/or arteries while maintaining hemostasis for a variety of diagnostic and therapeutic procedures. 8. Material of Construction: Polyurethane (PU), Polypropylene (PP), Acrylonitrile butadiene styrene (ABS) and Silicon 9. Dimension: Sheath 5F Radial - Length 11/9 cm, Sheath 5F Femoral - Length 11 cm, Sheath 6F Radial - Length 11/9 cm, Sheath 6F Femoral - Length 11 cm, Sheath 7F Femoral - Length 11 cm 10. Model/Catalogue No./Name :SLS/IFS/170101 - Introducer Femoral Sheath 4F (10 cm) ,SLS/IFS/170102 - Introducer Femoral Sheath 5F (11 cm) ,SLS/IFS/170103 - Introducer Femoral Sheath 6F (11 cm) ,SLS/IFS/170104 - Introducer Femoral Sheath 7F (11 cm) , SLS/IRS/180101 - Introducer Radial Sheath 4F (9 cm) ,SLS/IRS/180102 - Introducer Radial Sheath 5F (11 cm) ,SLS/IRS/180103 - Introducer Radial Sheath 6F (11 cm) ,SLS/IRS/180104 - Introducer Radial Sheath 7F (11 cm)

4	1. Generic Name :Angiographic Guide Wire 2. Brand Name :SEGURO/ULTIMA/MAGNA 3. Notified Category :Catheters 4. Class of Medical Device :Class D 5. Shelf life :3 Years 6. Sterile/Non-Sterile:Sterilized 7. Intended Use :Angiography guide wire is designed for percutaneous vessel entry using Seldinger Technique to facilitate the subsequent introduction of an intravascular device during Invasive Cardiology process. The corography guide wire is manufactured from stainless steel which could be coated with PTFE silicone or not. 8. Material of Construction: Stainless Steel 304 Medical grade which could be coated with PTFE silicone or not 9. Dimension: Length (150,180,260 ± 2cm), Outer Diameter 0.025", 0.032", 0.035", 0.038" (+0.0008"/-0.0016") 10. Model/Catalogue No./Name :SLS/AGW/201101 - Angiography Guide wire 0.025(in) x 150(cm) ST ,SLS/AGW/201102 - Angiography Guide wire 0.032(in) x 150(cm) ST , SLS/AGW/201103 - Angiography Guide wire 0.035(in) x 150(cm) ST ,SLS/AGW/201104 - Angiography Guide wire 0.038(in) x 150(cm) ST ,SLS/AGW/201105 - Angiography Guide wire 0.025(in) x 260(cm) ST ,SLS/AGW/201106 - Angiography Guide wire 0.032(in) x 260(cm) ST , SLS/AGW/201107 - Angiography Guide wire 0.035(in) x 260(cm) ST ,SLS/AGW/201108 - Angiography Guide wire 0.038(in) x 260(cm) ST ,SLS/AGW/201109 - Angiography Guide wire 0.025(in) x 150(cm) J ,SLS/AGW/201110 - Angiography Guide wire 0.032(in) x 150(cm) J , SLS/AGW/201111 - Angiography Guide wire 0.035(in) x 150(cm) J ,SLS/AGW/201112 - Angiography Guide wire 0.038(in) x 150(cm) J ,SLS/AGW/201113 - Angiography Guide wire 0.025(in) x 260(cm) J ,SLS/AGW/201114 - Angiography Guide wire 0.032(in) x 260(cm) J , SLS/AGW/201115 - Angiography Guide wire 0.035(in) x 260(cm) J ,SLS/AGW/201116 - Angiography Guide wire 0.038(in) x 260(cm) J ,SLS/AGW/201117 - Angiography Guide wire 0.035(in) x 180(cm) J ,SLS/AGW/201118 - Angiography Guide wire 0.025(in) x 150(cm) ST-N , SLS/AGW/201119 - Angiography Guide wire 0.032(in) x 150(cm) ST-N ,SLS/AGW/201120 - Angiography Guide wire 0.035(in) x 150(cm) ST-N ,SLS/AGW/201121 - Angiography Guide wire 0.038(in) x 150(cm) ST-N ,SLS/AGW/201122 - Angiography Guide wire 0.025(in) x 260 (cm) ST-N ,SLS/AGW/201123 - Angiography Guide wire 0.032(in) x 260(cm) ST-N , SLS/AGW/201124 - Angiography Guide wire 0.035(in) x 260(cm) ST-N ,SLS/AGW/201125 - Angiography Guide wire 0.038(in) x 260(cm) ST-N ,SLS/AGW/201126 - Angiography Guide wire 0.025(in) x 150(cm) J-N ,SLS/AGW/201127 - Angiography Guide wire 0.032(in) x 150 (cm) J-N ,SLS/AGW/201128 - Angiography Guide wire 0.035(in) x 150(cm) J-N , SLS/AGW/201129 - Angiography Guide wire 0.038(in) x 150(cm) J-N ,SLS/AGW/201130 - Angiography Guide wire 0.025(in) x 260(cm) J-N ,SLS/AGW/201131 - Angiography Guide wire 0.032(in) x 260(cm) J-N ,SLS/AGW/201132 - Angiography Guide wire 0.035(in) x 260 (cm) J-N ,SLS/AGW/201133 - Angiography Guide wire 0.038(in) x 260(cm) J-N
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Competent Authority