



FORM MD-9

[See sub-rule (1) rule 25]

Licence to Manufacture for Sale or for Distribution of Class C or Class D medical device

Licence Number: MFG/MD/2023/001015

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. The names, qualifications and experience of the competent technical staff responsible for the manufacture and testing of the above mentioned medical device(s): As per records maintain by the manufacturer

4. 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:Surgical Suture Model No.: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) Intended Use:Suture is indicated for use in general soft tissue approximation and/or ligation including cardiovascular surgery, neurosurgery and ophthalmic procedures including microsurgery. Class of medical device:Class C Material of construction:Thread of silkworm and Thread of Nylon, Stainless Steel 304 Medical Grade Dimension(if any):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) Shelflife:3 Years Sterile or Non sterile:Sterilized Brand Name(if registered under the Trade Marks Act, 1999):SEGURO/ULTIMA/MAGNA

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CONTROL ORGANIZATION, ou=RAJEEV SINGH
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2.5.4.20=80c62f6a23e4eafbe8a239774cdeb03c27
69041015a06564667f54b765db1cb,
postalCode=600034, st=TAMIL NADU,
serialNumber=657F5E47D940985D8F03BDC902D
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2	Generic Name:PTCA Balloon Catheter Model No.:SLS/BLN/120101 - PTCA Balloon Catheter 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. Class of medical device:Class C Material of construction:Stainless Steel 304medical grade, Polycarbonate (PC), Nylons Dimension(if any):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) Shelflife:3 Years Sterile or Non sterile:Sterilized Brand Name(if registered under the Trade Marks Act, 1999):SEGURO/ULTIMA/MAGNA
3	Generic Name:Introducer Radial/Femoral Sheath Model No.: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) 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. Class of medical device:Class C Material of construction:Polyurethane (PU), Polypropylene (PP), Acrylonitrile butadiene styrene (ABS) and Silicon Dimension(if any):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 Shelflife:3 Years Sterile or Non sterile:Sterilized Brand Name(if registered under the Trade Marks Act, 1999):SEGURO/ULTIMA/MAGNA

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 DN: cn=RAJEEV SINGH RAGHUVANSHI, o=RAJEEV SINGH RAGHUVANSHI, ou=RAJEEV SINGH RAGHUVANSHI, email=rajeev.singh.raghuvanshi@gmail.com, c=IN, postalCode=600034, st=TAMIL NADU, serialNumber=657F5E47D940985D8F038DC902D0E1FE73CFA12A1A126EA94FA5701124A19013, cn=RAJEEV SINGH RAGHUVANSHI
 Date: 2023.12.04 10:44:17 +05'30'

4	Generic Name:Angiographic Guide Wire Model No.: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 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. Class of medical device:Class D Material of construction:Stainless Steel 304 Medical grade which could be coated with PTFE silicone or not Dimension(if any):Length (150,180,260 ± 2cm), Outer Diameter 0.025", 0.032" , 0.035", 0.038" (+0.0008"/-0.0016") Shelflife:3 Years Sterile or Non sterile:Sterilized Brand Name(if registered under the Trade Marks Act, 1999):SEGUR	Digitally signed by RAJEEV SINGH RAGHUVANSHI DN: c=IN, o=CENTRAL DRUGS STANDARD CONTROL ORGANIZATION, ou=RAJEEV SINGH RAGHUVANSHI, 2.5.4.20=80c62f6a23e4efbe8a239774cdeb03c27 69041015a06564fe6754b765db1eb, postalCode=600034, st=TAMIL NADU, serialNumber=657F5E47D940985D8F03BDC902D 0E1FE73CFA12A1A126EA94FA5701124A19013, cn=RAJEEV SINGH RAGHUVANSHI Date: 2023.12.04 10:44:27 +05'30'
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Place:

Date04-Dec-23

Central Licensing Authority