



Ministerio de Salud
República Argentina

2026 - AÑO DE LA GRANDEZA ARGENTINA

DECLARACION JURADA

DISPOSICIÓN ANMAT N° 236/2026
DECRETO 895/25

N° rev: 1882-131#0001

En nombre y representación de la firma Bio Lap S.A , el responsable legal y el responsable técnico declaran bajo juramento cumplir con la Disposición 236/26 para el producto médico declarado bajo el Número de PM: 1882-131

Datos Característicos del Producto Médico:

Nombre descriptivo: Instrumental para cirugía estereotáctica

Código de identificación y nombre técnico del producto médico, (ECRI-UMDNS):
18-176 Sistemas Estereotáxicos

Marca(s) de (los) producto(s) médico(s): GLOBUS MEDICAL

Regla de clasificación Disposición ANMAT N° 64/25: Regla 6

Clase de Riesgo: II

Indicación/es de uso: El Instrumental está indicado para el uso en cirugía estereotáctica con el Navegador Quirúrgico Excelsius GPS

Modelos: 6143.2507 Bone Clamp with Surveillance Marker, Angled, Cranial-Caudal, GPS9143.0027 17mm Fixation Adapter & Drill Graphic Case, GPS6252.0001 Universal Array 16252.0002 Universal Array 26252.0003 Universal Array 36252.0004 Universal Array 46252.0005 Universal Array 56252.0006 Universal Array 66252.0007 Pilot Array 76252.0008 Pilot Array 86252.0009 Locking Threaded Shaft, Pilot Array 6252.0010 Dilator Array 96252.0043 Sleeve Adapter, 17mm, Probe, GPS6252.0044 Sleeve Adapter, 17mm, Tap, GPS6252.0050 Sleeve Adapter, 17mm, High Speed Drill, GPS6252.1125 Verification Adapter, Universal Array, FH, GPS6252.1231 TLIF Cup Curette, FH, GPS6252.1232 TLIF Cup Curette, 35° Right, FH, GPS6252.1233 TLIF Cup Curette, 35° Left, FH, GPS6252.1234 TLIF Cup Curette, 60° Up, FH, GPS6252.1235 TLIF Cup Curette, 60° Down, FH, GPS6252.1240 TLIF Double Rasp, 8mm, 35° Left, FH, GPS6252.1241 TLIF Double Rasp, Straight, 8mm, FH, GPS6252.1245 TLIF Rake,

8mm, 35° Left, FH, GPS6252.1250 TLIF Ring Curette, 6mm, 15° Up, FH, GPS6252.1251 TLIF Ring Curette, 6mm, 35° Right, 15° Up, FH, GPS6252.1252 TLIF Ring Curette, 6mm, 35° Left, 15° Up, FH, GPS6252.1255 TLIF Elevator, 6mm, FH, GPS6252.1260 TLIF Osteotome, 6mm, FH, GPS6252.1261 TLIF Osteotome, 7mm, FH, GPS6252.1262 TLIF Osteotome, 8mm, FH, GPS6252.1265 TLIF Paddle Distractor, 5mm, FH, GPS6252.1266 TLIF Paddle Distractor, 6mm, FH, GPS6252.1267 TLIF Paddle Distractor, 7mm, FH, GPS6252.1268 TLIF Paddle Distractor, 8mm, FH, GPS6252.1269 TLIF Paddle Distractor, 9mm, FH, GPS6252.1270 TLIF Paddle Distractor, 10mm, FH, GPS6252.1271 TLIF Paddle Distractor, 11mm, FH, GPS6252.1272 TLIF Paddle Distractor, 12mm, FH, GPS6252.1273 TLIF Paddle Distractor, 13mm, FH, GPS6252.1274 TLIF Paddle Distractor, 14mm, FH, GPS6252.1275 TLIF Paddle Distractor, 15mm, FH, GPS6252.1276 TLIF Paddle Distractor, 16mm, FH, GPS6252.1277 TLIF Paddle Distractor, 17mm, FH, GPS6252.1282 TLIF Sizer/Shaver, 5mm, FH, GPS6252.1283 TLIF Sizer/Shaver, 6mm, FH, GPS6252.1284 TLIF Sizer/Shaver, 7mm, FH, GPS6252.1285 TLIF Sizer/Shaver, 8mm, FH, GPS6252.1286 TLIF Sizer/Shaver, 9mm, FH, GPS6252.1287 TLIF Sizer/Shaver, 10mm, FH, GPS6252.1288 TLIF Sizer/Shaver, 11mm, FH, GPS6252.1289 TLIF Sizer/Shaver, 12mm, FH, GPS6252.1290 TLIF Sizer/Shaver, 13mm, FH, GPS6252.1291 TLIF Sizer/Shaver, 14mm, FH, GPS6252.1292 TLIF Sizer/Shaver, 15mm, FH, GPS6252.1293 TLIF Sizer/Shaver, 16mm, FH, GPS6252.1294 TLIF Sizer/Shaver, 17mm, FH, GPS6252.1390 TLIF Trial, 8mmx22mm, 5mm, FH, GPS6252.1391 TLIF Trial, 8mmx22mm, 6mm, FH, GPS6252.1392 TLIF Trial, 8mmx22mm, 7mm, FH, GPS6252.1393 TLIF Trial, 8mmx22mm, 8mm, FH, GPS6252.1394 TLIF Trial, 8mmx22mm, 9mm, FH, GPS6252.1395 TLIF Trial, 8mmx22mm, 10mm, FH, GPS6252.1396 TLIF Trial, 8mmx22mm, 11mm, FH, GPS6252.1397 TLIF Trial, 8mmx22mm, 12mm, FH, GPS6252.1398 TLIF Trial, 8mmx22mm, 13mm, FH, GPS6252.1399 TLIF Trial, 8mmx22mm, 14mm, FH, GPS6252.1400 TLIF Trial, 8mmx22mm, 15mm, FH, GPS6252.1401 TLIF Trial, 8mmx22mm, 16mm, FH, GPS6252.1402 TLIF Trial, 8mmx22mm, 17mm, FH, GPS6252.1405 TLIF Trial, 10mmx22mm, 5mm, FH, GPS6252.1406 TLIF Trial, 10mmx22mm, 6mm, FH, GPS6252.1407 TLIF Trial, 10mmx22mm, 7mm, FH, GPS6252.1408 TLIF Trial, 10mmx22mm, 8mm, FH, GPS6252.1409 TLIF Trial, 10mmx22mm, 9mm, FH, GPS6252.1410 TLIF Trial, 10mmx22mm, 10mm, FH, GPS6252.1411 TLIF Trial, 10mmx22mm, 11mm, FH, GPS6252.1412 TLIF Trial, 10mmx22mm, 12mm, FH, GPS6252.1413 TLIF Trial, 10mmx22mm, 13mm, FH, GPS6252.1414 TLIF Trial, 10mmx22mm, 14mm, FH, GPS6252.1415 TLIF Trial, 10mmx22mm, 15mm, FH, GPS6252.1416 TLIF Trial, 10mmx22mm, 16mm, FH, GPS6252.1417 TLIF Trial, 10mmx22mm, 17mm, FH, GPS6252.1460 Insertor Body, RISE/CALIBER Insertor, FH, GPS6252.1501 Outer Sleeve, SABLE Insertor, FH, GPS6252.1502 Threaded Shaft, SABLE Insertor, FH, GPS6252.1505 Rigid Driver, SABLE Instruments6252.1506 Bone Funnel Tube, SABLE Instruments6252.1507 Graft Plunger, SABLE Instruments6252.1510 Suction Tip, SABLE Instruments6252.1518 Posterior Lordotic Trial, 8°, FH, GPS6252.1519 Posterior Lordotic Trial, 15°, FH, GPS6252.1520 Posterior Lordotic Trial, 22°, FH, GPS6252.1522 Driver 22mm, SABLE Insertor, FH, GPS6252.1526 Driver 26mm, SABLE Insertor, FH, GPS6252.1530 Driver 30mm, SABLE Insertor, FH, GPS6252.1534 Driver 34mm, SABLE Insertor, FH, GPS6252.1535 Verification Adapter, SABLE Insertor, FH, GPS6252.1561 Cohere TLIF-O Insertor, FH, GPS6252.1565 Verification Adapter, Cohere TLIF-O Insertor6252.1571 HEDRON P Insertor, Outer Sleeve, FH, GPS6252.1572 HEDRON P Insertor, Threaded Shaft, FH, GPS6252.1575 Verification Adapter, HEDRON P Insertor6252.1581 Modulus TLIF-O Insertor, FH, GPS6252.1585 Verification Adapter, Modulus TLIF-O Insertor6252.4244 RELINE Modular TLIF Screwdriver Shaft, Cannulated, FH, GPS6252.5005 10.5mm Tap, FH, GPS6252.5006 10.5mm Cannulated Tap, FH, GPS6252.5007 10.5mm Awl-Tip Tap, FH, GPS6252.5040 4.0mm Tap, FH, GPS6252.5042 4.0mm Awl-Tip Tap, FH, GPS6252.5045 4.5mm Tap, FH, GPS6252.5046 4.5mm Cannulated Tap, FH, GPS6252.5047 4.5mm Awl-Tip Tap, FH, GPS6252.5050 5.0mm Tap, FH, GPS6252.5051 5.0mm Cannulated Tap, FH, GPS6252.5052 5.0mm Awl-Tip Tap, FH, GPS6252.5055 5.5mm Tap, FH, GPS6252.5056 5.5mm Cannulated Tap, FH, GPS6252.5057

5.5mm Awl-Tip Tap, FH, GPS6252.5062 6.0mm Awl-Tip Tap, FH, GPS6252.5065 6.5mm Tap, FH, GPS6252.5066 6.5mm Cannulated Tap, FH, GPS6252.5067 6.5mm Awl-Tip Tap, FH, GPS6252.5075 7.5mm Tap, FH, GPS6252.5076 7.5mm Cannulated Tap, FH, GPS6252.5077 7.5mm Awl-Tip Tap, FH, GPS6252.5085 8.5mm Tap, FH, GPS6252.5086 8.5mm Cannulated Tap, FH, GPS6252.5087 8.5mm Awl-Tip Tap, FH, GPS6252.5095 9.5mm Tap, FH, GPS6252.5096 9.5mm Cannulated Tap, FH, GPS6252.5097 9.5mm Awl-Tip Tap, FH, GPS6252.5200 CREO AMP Rigid Screwdriver Shaft, FH, GPS6252.5201 CREO AMP Cannulated Rigid Screwdriver Shaft, FH, GPS6252.5205 CREO AMP Rigid Screwdriver Outer Sleeve, FH, GPS6252.5220 CREO NXT Rigid Screwdriver Shaft, FH, GPS6252.5221 CREO NXT Cannulated Rigid Screwdriver Shaft, FH, GPS6252.5225 CREO NXT Rigid Screwdriver Outer Sleeve, FH, GPS6252.5230 CREO DLX Rigid Screwdriver Shaft, FH, GPS6252.5231 CREO DLX Cannulated Rigid Screwdriver Shaft, FH, GPS6252.5233 CREO DLX Rigid Reduction Screwdriver Shaft, FH, GPS6252.5234 CREO DLX Cannulated Rigid Reduction Screwdriver Shaft, FH, GPS6252.5235 CREO DLX Rigid Screwdriver Outer Sleeve, FH, GPS6252.5238 CREO DLX Rigid Reduction Screwdriver Outer Sleeve, FH, GPS6252.5240 CREO Rigid Screwdriver Shaft, FH, GPS6252.5241 CREO Rigid Screwdriver Shaft, Cannulated, FH, GPS6252.5245 CREO 4.75 Rigid Screwdriver Outer Sleeve, FH, GPS6252.5246 CREO 4.75 Threaded Rigid Driver Counter Torque, FH, GPS6252.5248 CREO 4.75 Rigid Reduction Screwdriver Outer Sleeve, FH, GPS6252.5255 CREO 5.5 Rigid Screwdriver Outer Sleeve, FH, GPS6252.5256 CREO 5.5 Rigid Driver Counter Torque, FH, GPS6252.5260 CREO 5.5 Rigid Screwdriver Shaft, Threaded, FH, GPS6252.5261 CREO 5.5 Cannulated Rigid Screwdriver Shaft, Threaded, FH, GPS6252.5265 CREO 5.5 Rigid Screwdriver Outer Sleeve, Threaded, FH, GPS6252.5268 CREO 5.5 Rigid Reduction Screwdriver Outer Sleeve, Threaded, FH, GPS6252.5270 CREO MIS Driver Shaft, FH, GPS6252.5271 CREO MIS Cannulated Driver Shaft, FH, GPS6252.5276 CREO MIS Driver Outer Sleeve, 10mm, FH, GPS6252.5277 CREO MIS Driver Outer Sleeve, 30mm, FH, GPS6252.5290 CREO S2AI Rigid Screwdriver Shaft, FH, GPS6252.5291 CREO S2AI Cannulated Rigid Screwdriver Shaft, FH, GPS6252.5295 CREO S2AI Rigid Screwdriver Outer Sleeve, FH, GPS6252.5340 CREO 4.75 Monoaxial Rigid Screwdriver, Threaded, FH, GPS6252.5350 CREO 5.5 Monoaxial Rigid Screwdriver, FH, GPS6252.5360 CREO 5.5 Monoaxial Rigid Screwdriver, Threaded, FH, GPS6252.5600 Drill Guide, FH, GPS6252.5605 Alignment Fork, Drill Guide, FH, GPS6252.5610 Depth Stop, Drill Guide, FH, GPS6252.5625 2.5mm Drill, FH, GPS6252.5626 2.5mm Reaming Pilot Drill, FH, GPS6252.5635 3.5mm Drill, FH, GPS6252.5636 3.5mm Reaming Pilot Drill, FH, GPS6252.5645 4.5mm Drill, FH, GPS6252.5646 4.5mm Reaming Pilot Drill, FH, GPS6252.5655 5.5mm Drill, FH, GPS6252.5656 5.5mm Reaming Pilot Drill, FH, GPS6252.5700 Pedicle Awl, FH, GPS6252.5701 MIS Awl, FH, GPS6252.5702 MIS Awl, Cannulated for 1.6mm K-Wire, FH, GPS6252.5703 Capped Guidewire, 1.6mm, FH, GPS6252.5710 Pedicle Probe, Straight, FH, GPS6252.5715 Pedicle Probe, Curved, FH, GPS6252.5720 Thoracic Probe, Straight, FH, GPS6252.5725 Thoracic Probe, Curved, FH, GPS6252.6030 Tap for 3.0mm Screw, FH, GPS6252.6035 Tap for 3.5mm Screw, FH, GPS6252.6040 Tap for 4.0mm Screw, FH, GPS6252.6045 Tap for 4.5mm Screw, FH, GPS6252.6050 Tap for 5.0mm Screw, FH, GPS6252.6055 Tap for 5.5mm Screw, FH, GPS6252.6060 Tap for 6.0mm Screw, FH, GPS6252.6065 Tap for 6.5mm Screw, FH, GPS6252.6110 ELLIPSE Polyaxial Screwdriver, FH, GPS6252.6132 QUARTEX Rigid Screwdriver, FH, GPS6252.6600 Cervical Drill Guide, FH, GPS6252.6610 Depth Stop, Cervical Drill Guide, FH, GPS6252.6630 Drill Bit for 3.0mm Screw, FH, GPS6252.6631 Drill Bit for 3.0mm Screw, Short, FH, GPS6252.6635 Drill Bit for 3.5mm Screw, FH, GPS6252.6636 Drill Bit for 3.5mm Screw, Short, FH, GPS6252.6640 Drill Bit for 4.0mm Screw, FH, GPS6252.6641 Drill Bit for 4.0mm Screw, Short, FH, GPS6252.6645 Drill Bit for 4.5mm Screw, FH, GPS6252.6700 Cervical Pedicle Awl, FH, GPS6252.6710 Cervical Pedicle Probe, FH, GPS6252.6715 Cervical Pedicle Probe, Curved, FH, GPS6252.7006 SI-LOK Cannulated Tap, 10.0mm Screw, FH, GPS6252.7011 6mm Universal Initial Dilator, Cannulated, FH, GPS6252.7012 7mm Dilator,

MARS Ports6252,7013 9mm Dilator, MARS Ports6252,7014 6mm Universal Initial Dilator, Non-Cannulated, FH, GPS6252,7081 SI-LOK Cannulated Tap, 8.0mm Screw, FH, GPS6252,7201 T27 Cannulated Shaft, SI-LOK Select Driver, FH, GPS6252,7205 Outer Sleeve, SI-LOK Select Driver, FH, GPS6252,7211 4.0mm Hex Cannulated Shaft, SI-LOK Driver, FH, GPS6252,7215 Outer Sleeve, SI-LOK Driver, FH, GPS6252,7216 Threaded Cap, SI-LOK Driver, FH, GPS6252,7605 SI-LOK Drill, 10.5mm, FH, GPS6252,7606 SI-LOK Cannulated Drill, 10.5mm, FH, GPS6252,7665 SI-LOK Drill, 6.5mm, FH, GPS6252,7666 SI-LOK Cannulated Drill, 6.5mm, FH, GPS6252,7675 SI-LOK Drill, 7.5mm, FH, GPS6252,7676 SI-LOK Cannulated Drill, 7.5mm, FH, GPS6252,7685 SI-LOK Drill, 8.5mm, FH, GPS6252,7686 SI-LOK Cannulated Drill, 8.5mm, FH, GPS6252,7695 SI-LOK Drill, 9.5mm, FH, GPS6252,7696 SI-LOK Cannulated Drill, 9.5mm, FH, GPS6252,7702 MIS Awl, Cannulated for 2.4mm K-Wire, FH, GPS6252,7703 Capped Guide Wire, 2.4mm, FH, GPS9252.0001 Excelsius Array Graphic Case9252,0002 Spine Registration Set Graphic Case9252,0004 CREO Pedicle Prep Set Graphic Case, Hub9252,0005 CREO Optimized, Hub, Graphic Case9252,0008 SI-LOK, Freehand, GPS Graphic Case9252,0009 Quartex, HUB Graphic Case9252,0017 Graphic Case, Excelsius Interbody Set, Hub, GPS9252.0070 RELINE Pedicle Prep & Driver Set, HUB Graphic Case9252,0071 RELINE MAS Guide Graphic Case, HUB9252,0072 RELINE MAS Midline Graphic Case, HUB9252,0073 RELINE Small Stature Graphic Case, FH, GPS9252,0080 RELINE CERVICAL Graphic Case, Hub9252,2519 Posterior Disc Prep, Hub, GPS Graphic Case9252,2522 RISE Instrument Set, Hub, GPS Graphic Case9252,2523 SABLE Instrument Set, Hub, GPS Graphic Case9252.2525 Posterior Trials, Hub, GPS Graphic Case9252,2526 COHERE TLIF-O Instrument Set, Hub, GPS Graphic Case9252,2527 HEDRON P Instrument Set, Hub, GPS Graphic Case9252.2528 MODULUS TLIF-O Instrument Set, Hub, GPS Graphic Case6255.0001 Slap Hammer6255.0005 T-Handle, IBF6255.0007 Straight Handle, IBF6255.0010 Lateral Cobb, 10mm, FH, GPS6255.0011 Lateral Cobb, 10mm, 7° Up, FH, GPS6255.0015 Lateral Ring Curette, 10mm, FH, GPS6255.0016 Lateral Osteotome, Straight, 1/2 Inch, FH, GPS6255.0017 Lateral Ring Curette, 10mm, 7° Up, FH, GPS6255.0018 Lateral Cobb, 18mm, FH, GPS6255,0019 Lateral Cobb, 18mm, 7° Up, FH, GPS6255.0020 Lateral Cobb, 20mm, FH, GPS6255,0021 Lateral Cobb, 20mm, 7° Up, FH, GPS6255,0022 Lateral Cobb, 22mm, FH, GPS6255,0023 Lateral Cobb, 22mm, 7° Up, FH, GPS6255.0030 Lateral Double Rasp, FH, GPS6255,0032 AMS XLIF Inserter, FH, GPS6255,0033 AMS XLIF Inserter Driver, FH, GPS6255,0034 Verification Adapter, AMS XLIF, FH, GPS6255.0040 Lateral Distractor, 4mm, FH, GPS6255,0041 Lateral Distractor, 6mm, FH, GPS6255,0042 Lateral Distractor, 8mm, FH, GPS6255,0054 Lateral Rake, FH, GPS6255,0075 HEDRON-L Inserter, FH, GPS6255,0076 HEDRON-L Inserter Driver, FH, GPS6255.0077 Verification Adapter, HEDRON-L, FH, GPS6255,0083 Lateral Box Cutter, 16x4mm, FH, GPS6255,0085 Lateral Box Cutter, 16x6mm, FH, GPS6255,0087 Lateral Box Cutter, 16x8mm, FH, GPS6255,0088 Lateral Cup Curette, Serrated, FH, GPS6255,0089 Lateral Cup Curette, 15° Up, Serrated, FH, GPS6255.0090 Lateral Cup Curette, 90° Up, Serrated, FH, GPS6255,0091 Lateral Cup Curette, 90° Down, Serrated, FH, GPS6255,0093 RISE-L/ELSA Inserter, FH, GPS6255,0094 Torque Limiting Driver, 3.0Nm, RISE-L/ELSA Inserter, FH, GPS6255,0105 Lateral Trial, 18 x 40-60mm, 5mm, Parallel, FH, GPS6255,0107 Lateral Trial, 18 x 40-60mm, 7mm, Parallel, FH, GPS6255,0109 Lateral Trial, 18 x 40-60mm, 9mm, Parallel, FH, GPS6255,0111 Lateral Trial, 18 x 40-60mm, 11mm, Parallel, FH, GPS6255,0113 Lateral Trial, 18 x 40-60mm, 13mm, Parallel, FH, GPS6255,0115 Lateral Trial, 18 x 40-60mm, 15mm, Parallel, FH, GPS6255,0117 Lateral Trial, 18 x 40-60mm, 17mm, Parallel, FH, GPS6255,0205 Lateral Trial, 20 x 35-65mm, 5mm, Parallel, FH, GPS6255,0207 Lateral Trial, 20 x 35-65mm, 7mm, Parallel, FH, GPS6255,0209 Lateral Trial, 20 x 35-65mm, 9mm, Parallel, FH, GPS6255,0211 Lateral Trial, 20 x 35mm, 11mm, Parallel, FH, GPS6255,0213 Lateral Trial, 20 x 35mm, 13mm, Parallel, FH, GPS6255,0215 Lateral Trial, 20 x 35mm, 15mm, Parallel, FH, GPS6255,0217 Lateral Trial, 20 x 35mm, 17mm, Parallel, FH, GPS6255,0305 Lateral Scraper, 5mm, FH, GPS6255,0307 Lateral Scraper, 7mm, FH, GPS6255,0309 Lateral Scraper, 9mm, FH, GPS6255,0311 Lateral Scraper,

11mm, FH, GPS6255,0313 Lateral Scraper, 13mm, FH, GPS6255,0315 Lateral Scraper, 15mm, FH, GPS6255,0317 Lateral Scraper, 17mm, FH, GPS6255,0328 XLIF Shim Insert, FH, GPS6255,0405 Lateral Trial, 22 x 40-60mm, 5mm, Parallel, FH, GPS6255,0407 Lateral Trial, 22 x 40-60mm, 7mm, Parallel, FH, GPS6255,0409 Lateral Trial, 22 x 40-60mm, 9mm, Parallel, FH, GPS6255,0411 Lateral Trial, 22 x 40-60mm, 11mm, Parallel, FH, GPS6255,0413 Lateral Trial, 22 x 40-60mm, 13mm, Parallel, FH, GPS6255,0415 Lateral Trial, 22 x 40-60mm, 15mm, Parallel, FH, GPS6255,0417 Lateral Trial, 22 x 40-60mm, 17mm, Parallel, FH, GPS6255,1105 Lateral Trial, 18 x 40-60mm, 5mm, 10°, FH, GPS6255,1107 Lateral Trial, 18 x 40-60mm, 7mm, 10°, FH, GPS6255,1108 AMS XLIF Trial, 8x18mm, 10°, FH, GPS6255,1109 Lateral Trial, 18 x 40-60mm, 9mm, 10°, FH, GPS6255,1110 AMS XLIF Trial, 10x18mm, 10°, FH, GPS6255,1111 Lateral Trial, 18 x 40-60mm, 11mm, 10°, FH, GPS6255,1112 AMS XLIF Trial, 12x18mm, 10°, FH, GPS6255,1113 Lateral Trial, 18 x 40-60mm, 13mm, 10°, FH, GPS6255,1115 Lateral Trial, 18 x 40-60mm, 15mm, 10°, FH, GPS6255,1117 Lateral Trial, 18 x 40-60mm, 17mm, 10°, FH, GPS6255,1405 Lateral Trial, 22 x 40-60mm, 5mm, 10°, FH, GPS6255,1407 Lateral Trial, 22 x 40-60mm, 7mm, 10°, FH, GPS6255,1408 AMS XLIF Trial, 8x22mm, 10°, FH, GPS6255,1409 Lateral Trial, 22 x 40-60mm, 9mm, 10°, FH, GPS6255,1410 AMS XLIF Trial, 10x22mm, 10°, FH, GPS6255,1411 Lateral Trial, 22 x 40-60mm, 11mm, 10°, FH, GPS6255,1412 AMS XLIF Trial, 12x22mm, 10°, FH, GPS6255,1413 Lateral Trial, 22 x 40-60mm, 13mm, 10°, FH, GPS6255,1415 Lateral Trial, 22 x 40-60mm, 15mm, 10°, FH, GPS6255,1417 Lateral Trial, 22 x 40-60mm, 17mm, 10°, FH, GPS6255,1501 Lateral Cobb, 10mm, CC Angled, Down, FH, GPS6255,1502 Lateral Cobb, 10mm, CC Angled, Up, FH, GPS6255,1505 Lateral Trial, 18 x 40-60, 5mm, Parallel, CC Angled, FH, GPS6255,1507 Lateral Trial, 18 x 40-60, 7mm, Parallel, CC Angled, FH, GPS6255,1509 Lateral Trial, 18 x 40-60, 9mm, Parallel, CC Angled, FH, GPS6255,1511 Lateral Trial, 18 x 40-60, 11mm, Parallel, CC Angled, FH, GPS6255,1513 Lateral Trial, 18 x 40-60, 13mm, Parallel, CC Angled, FH, GPS6255,1515 Lateral Trial, 18 x 40-60, 15mm, Parallel, CC Angled, FH, GPS6255,1516 Lateral Osteotome, 1/2 Inch, CC Angled, FH, GPS6255,1517 Lateral Trial, 18 x 40-60, 17mm, Parallel, CC Angled, FH, GPS6255,1518 Lateral Cobb, 18mm, CC Angled, Down, FH, GPS6255,1519 Lateral Cobb, 18mm, CC Angled, Up, FH, GPS6255,1520 Lateral Cobb, 20mm, CC Angled, Down, FH, GPS6255,1521 Lateral Cobb, 20mm, CC Angled, Up, FH, GPS6255,1522 Lateral Cobb, 22mm, CC Angled, Down, FH, GPS6255,1523 Lateral Cobb, 22mm, CC Angled, Up, FH, GPS6255,1530 Lateral Double Rasp, CC Angled, FH, GPS6255,1532 15° Angled Lateral Insert, AMS XLIF, FH, GPS6255,1540 Lateral Distractor, 4mm, CC Angled, FH, GPS6255,1541 Lateral Distractor, 6mm, CC Angled, FH, GPS6255,1542 Lateral Distractor, 8mm, CC Angled, FH, GPS6255,1554 Lateral Rake, CC Angled, FH, GPS6255,1575 15° Angled Lateral Insert, HEDRON L, FH, GPS6255,1583 Lateral Box Cutter, 16x4mm, CC Angled, FH, GPS6255,1585 Lateral Box Cutter, 16x6mm, CC Angled, FH, GPS6255,1587 Lateral Box Cutter, 16x8mm, CC Angled, FH, GPS6255,1588 Lateral Cup Curette, CC Angled, Down, Serrated, FH, GPS6255,1589 Lateral Cup Curette, CC Angled, Up, Serrated, FH, GPS6255,1593 15° Angled Lateral Insert, Expandable, FH, GPS6255,2005 Lateral Trial, 20 x 35-60, 5mm, Parallel, ATP Angled, FH, GPS6255,2007 Lateral Trial, 20 x 35-60, 7mm, Parallel, ATP Angled, FH, GPS6255,2009 Lateral Trial, 20 x 35-60, 9mm, Parallel, ATP Angled, FH, GPS6255,2011 Lateral Trial, 20 x 35-60, 11mm, Parallel, ATP Angled, FH, GPS6255,2013 Lateral Trial, 20 x 35-60, 13mm, Parallel, ATP Angled, FH, GPS6255,2015 Lateral Trial, 20 x 35-60, 15mm, Parallel, ATP Angled, FH, GPS6255,2017 Lateral Trial, 20 x 35-60, 17mm, Parallel, ATP Angled, FH, GPS6255,2105 Lateral Trial, 18 x 40-60, 5mm, Parallel, ATP Angled, FH, GPS6255,2107 Lateral Trial, 18 x 40-60, 7mm, Parallel, ATP Angled, FH, GPS6255,2109 Lateral Trial, 18 x 40-60, 9mm, Parallel, ATP Angled, FH, GPS6255,2111 Lateral Trial, 18 x 40-60, 11mm, Parallel, ATP Angled, FH, GPS6255,2113 Lateral Trial, 18 x 40-60, 13mm, Parallel, ATP Angled, FH, GPS6255,2115 Lateral Trial, 18 x 40-60, 15mm, Parallel, ATP Angled, FH, GPS6255,2117 Lateral Trial, 18 x 40-60, 17mm, Parallel, ATP Angled, FH, GPS6255,2205 Lateral Trial, 22 x 40-60, 5mm, Parallel, ATP Angled, FH, GPS6255,2207 Lateral

Trial, 22 x 40-60, 7mm, Parallel, ATP Angled, FH, GPS6255,2209 Lateral Trial, 22 x 40-60, 9mm, Parallel, ATP Angled, FH, GPS6255,2211 Lateral Trial, 22 x 40-60, 11mm, Parallel, ATP Angled, FH, GPS6255,2213 Lateral Trial, 22 x 40-60, 13mm, Parallel, ATP Angled, FH, GPS6255,2215 Lateral Trial, 22 x 40-60, 15mm, Parallel, ATP Angled, FH, GPS6255,2217 Lateral Trial, 22 x 40-60, 17mm, Parallel, ATP Angled, FH, GPS6255,2309 Lateral Trial, 20 x 35-60, 9mm, 10°, ATP Angled, FH, GPS6255,2311 Lateral Trial, 20 x 35-60, 11mm, 10°, ATP Angled, FH, GPS6255,2313 Lateral Trial, 20 x 35-60, 13mm, 10°, ATP Angled, FH, GPS6255,2315 Lateral Trial, 20 x 35-60, 15mm, 10°, ATP Angled, FH, GPS6255,2317 Lateral Trial, 20 x 35-60, 17mm, 10°, ATP Angled, FH, GPS6255,2503 Lateral Double Rasp, 12 x 20mm, ATP Angled, FH, GPS6255,2510 Lateral Cobb, 10mm, ATP Angled, Up, FH, GPS6255,2511 Lateral Cobb, 10mm, ATP Angled, Down, FH, GPS6255,2514 Lateral Osteotome, 1/2 Inch, ATP Angled, Down, FH, GPS6255,2515 Lateral Double Ring Curette, 10mm, ATP Angled, FH, GPS6255,2516 Lateral Ring Curette, 10mm, 7°, ATP Angled, Down, FH, GPS6255,2517 Lateral Ring Curette, 10mm, 7°, ATP Angled, Up, FH, GPS6255,2520 Lateral Cobb, 20mm, ATP Angled, Down, FH, GPS6255,2521 Lateral Cobb, 20mm, ATP Angled, Up, FH, GPS6255,2522 Lateral Cobb, 20mm, 7°, ATP Angled, Down, FH, GPS6255,2523 Lateral Cobb, 20mm, 7°, ATP Angled, Up, FH, GPS6255,2524 Lateral Cobb, 18mm, ATP Angled, Down, FH, GPS6255,2525 Lateral Cobb, 18mm, ATP Angled, Up, FH, GPS6255,2526 Lateral Cobb, 22mm, ATP Angled, Down, FH, GPS6255,2527 Lateral Cobb, 22mm, ATP Angled, Up, FH, GPS6255,2530 Lateral Cobb, 10mm, 7°, ATP Angled, Down, FH, GPS6255,2531 Lateral Cobb, 10mm, 7°, ATP Angled, Up, FH, GPS6255,2532 25° Angled Lateral Insertor, AMS XLIF, FH, GPS6255,2540 Lateral Distractor, 4mm, ATP Angled, FH, GPS6255,2541 Lateral Distractor, 6mm, ATP Angled, FH, GPS6255,2542 Lateral Distractor, 8mm, ATP Angled, FH, GPS6255,2554 Lateral Rake, ATP Angled, FH, GPS6255,2575 25° Angled Lateral Insertor, Static, FH, GPS6255,2587 Lateral Cup Curette, ATP Angled, Down, FH, GPS6255,2588 Lateral Cup Curette, ATP Angled, Up, FH, GPS6255,2589 Lateral Cup Curette, ATP Angled, Down, 15°, FH, GPS6255,2590 Lateral Cup Curette, ATP Angled, Up, Serrated, 15°, FH, GPS6255,2593 25° Angled Lateral Insertor, Expandable, FH, GPS6255,2605 Lateral Trial, 20 x 35-60, 5mm, 6°, ATP Angled, FH, GPS6255,2607 Lateral Trial, 20 x 35-60, 7mm, 6°, ATP Angled, FH, GPS6255,2609 Lateral Trial, 20 x 35-60, 9mm, 6°, ATP Angled, FH, GPS6255,2705 Lateral Trial, 18 x 40-60, 5mm, 6°, ATP Angled, FH, GPS6255,2707 Lateral Trial, 18 x 40-60, 7mm, 6°, ATP Angled, FH, GPS6255,2709 Lateral Trial, 18 x 40-60, 9mm, 6°, ATP Angled, FH, GPS6255,2711 Lateral Trial, 18 x 40-60, 11mm, 6°, ATP Angled, FH, GPS6255,2713 Lateral Trial, 18 x 40-60, 13mm, 6°, ATP Angled, FH, GPS6255,2715 Lateral Trial, 18 x 40-60, 15mm, 6°, ATP Angled, FH, GPS6255,2717 Lateral Trial, 18 x 40-60, 17mm, 6°, ATP Angled, FH, GPS6255,2805 Lateral Trial, 22 x 40-60, 5mm, 6°, ATP Angled, FH, GPS6255,2807 Lateral Trial, 22 x 40-60, 7mm, 6°, ATP Angled, FH, GPS6255,2809 Lateral Trial, 22 x 40-60, 9mm, 6°, ATP Angled, FH, GPS6255,2811 Lateral Trial, 22 x 40-60, 11mm, 6°, ATP Angled, FH, GPS6255,2813 Lateral Trial, 22 x 40-60, 13mm, 6°, ATP Angled, FH, GPS6255,2815 Lateral Trial, 22 x 40-60, 15mm, 6°, ATP Angled, FH, GPS6255,2817 Lateral Trial, 22 x 40-60, 17mm, 6°, ATP Angled, FH, GPS6255,3408 AMS XLIF Trial, 8x22mm, 5°, FH, GPS6255,3410 AMS XLIF Trial, 10x22mm, 5°, FH, GPS6255,3412 AMS XLIF Trial, 12x22mm, 5°, FH, GPS6255,4505 Lateral Trial, 22 x 40-60, 5mm, Parallel, CC Angled, FH, GPS6255,4507 Lateral Trial, 22 x 40-60, 7mm, Parallel, CC Angled, FH, GPS6255,4509 Lateral Trial, 22 x 40-60, 9mm, Parallel, CC Angled, FH, GPS6255,4511 Lateral Trial, 22 x 40-60, 11mm, Parallel, CC Angled, FH, GPS6255,4513 Lateral Trial, 22 x 40-60, 13mm, Parallel, CC Angled, FH, GPS6255,4515 Lateral Trial, 22 x 40-60, 15mm, Parallel, CC Angled, FH, GPS6255,4517 Lateral Trial, 22 x 40-60, 17mm, Parallel, CC Angled, FH, GPS6255,5107 Lateral Trial, 18 x 40-60mm, 7mm, 15°, FH, GPS6255,5109 Lateral Trial, 18 x 40-60mm, 9mm, 15°, FH, GPS6255,5111 Lateral Trial, 18 x 40-60mm, 11mm, 15°, FH, GPS6255,5113 Lateral Trial, 18 x 40-60mm, 13mm, 15°, FH, GPS6255,5115 Lateral Trial, 18 x 40-60mm, 15mm, 15°, FH, GPS6255,5117 Lateral Trial, 18 x 40-60mm, 17mm, 15°, FH, GPS6255,5211 Lateral Trial, 20 x 35-65mm, 11mm, 15°, FH,

GPS6255,5407 Lateral Trial, 22 x 40-60mm, 7mm, 15°, FH, GPS6255,5408 AMS XLIF Trial, 8x22mm, 15°, FH, GPS6255,5409 Lateral Trial, 22 x 40-60mm, 9mm, 15°, FH, GPS6255,5410 AMS XLIF Trial, 10x22mm, 15°, FH, GPS6255,5411 Lateral Trial, 22 x 40-60mm, 11mm, 15°, FH, GPS6255,5412 AMS XLIF Trial, 12x22mm, 15°, FH, GPS6255,5413 Lateral Trial, 22 x 40-60mm, 13mm, 15°, FH, GPS6255,5415 Lateral Trial, 22 x 40-60mm, 15mm, 15°, FH, GPS6255,5417 Lateral Trial, 22 x 40-60mm, 17mm, 15°, FH, GPS6255,5419 Lateral Trial, 22 x 40-60mm, 19mm, 15°, FH, GPS6255,6105 Lateral Trial, 18 x 40-60mm, 5mm, 6°, FH, GPS6255,6107 Lateral Trial, 18 x 40-60mm, 7mm, 6°, FH, GPS6255,6109 Lateral Trial, 18 x 40-60mm, 9mm, 6°, FH, GPS6255,6111 Lateral Trial, 18 x 40-60mm, 11mm, 6°, FH, GPS6255,6113 Lateral Trial, 18 x 40-60mm, 13mm, 6°, FH, GPS6255,6115 Lateral Trial, 18 x 40-60mm, 15mm, 6°, FH, GPS6255,6117 Lateral Trial, 18 x 40-60mm, 17mm, 6°, FH, GPS6255,6205 Lateral Trial, 20 x 35-65mm, 5mm, 6°, FH, GPS6255,6207 Lateral Trial, 20 x 35-65mm, 7mm, 6°, FH, GPS6255,6209 Lateral Trial, 20 x 35-65mm, 9mm, 6°, FH, GPS6255,6405 Lateral Trial, 22 x 40-60mm, 5mm, 6°, FH, GPS6255,6407 Lateral Trial, 22 x 40-60mm, 7mm, 6°, FH, GPS6255,6409 Lateral Trial, 22 x 40-60mm, 9mm, 6°, FH, GPS6255,6411 Lateral Trial, 22 x 40-60mm, 11mm, 6°, FH, GPS6255,6413 Lateral Trial, 22 x 40-60mm, 13mm, 6°, FH, GPS6255,6415 Lateral Trial, 22 x 40-60mm, 15mm, 6°, FH, GPS6255,6417 Lateral Trial, 22 x 40-60mm, 17mm, 6°, FH, GPS6255.7012 9mm Dilator, XLIF6255,7013 12mm Dilator, XLIF9255.0010 Lateral Disc Prep Set, Hub, GPS Graphic Case9255,0011 RISE-L & ELSA, Hub, GPS Graphic Case9255,0012 HEDRON L, Hub, GPS Graphic Case9255,0013 Cephalad-Caudal Angled Lateral Disc Prep, Hub, GPS Graphic Case9255,0014 Cephalad-Caudal Angled Lateral Insertion, Hub, GPS Graphic Case9255,0015 Anterolateral Angled Disc Prep, Hub, GPS Graphic Case9255,0016 Anterolateral Angled Insertion, Hub, GPS Graphic Case9255,0017 Anterolateral Angled Trials, Hub, GPS Graphic Case9255.0018 HEDRON L 15° Trials, Hub, GPS Graphic Case9255,0019 AMS XLIF Insertion Graphic Case, Hub, GPS6210.2007 Spanner Wrench

Composición cuali-cuanti porcentual exacta (si corresponde): NA

Período de vida útil: 5 años

Condición de uso: Uso exclusivo a profesionales e instituciones sanitarias

Contiene látex: NO

Forma de presentación: Unitaria

Método de esterilización: NA

Condición de conservación/almacenamiento (SI CORRESPONDE): NA

Nombre del fabricante: GLOBUS MEDICAL INC

Lugar de elaboración: 2560 General Armistead Ave VALLEY FORGE BUSINESS CENTER
AUDUBON, PA 19403 Estados Unidos

El responsable legal y su responsable técnico son responsables de la veracidad de la documentación e información presentada y declaran bajo juramento que el producto médico, que cumple y satisface con los Requisitos Esenciales de Seguridad y Desempeño (R.E.S.D.) previstos por la Disposición ANMAT N° 11467/24.

La empresa mantiene en su establecimiento y a disposición de la autoridad sanitaria la documentación requerida por Disposición ANMAT N°236/26, Disposición ANMAT N°64/25 y Disposición ANMAT N° 9688/19.

Firma del Responsable Legal

Firme Responsable Técnico

La presente DECLARACIÓN JURADA ha sido emitida de acuerdo con las previsiones del Decreto 892/25 y la Disposición ANMAT N° 236/26, quedando en el Registro Nacional de Productores y Productos de Tecnología Médica (R.P.P.T.M.) a favor de Bio Lap S.A bajo el número PM 1882-131, siendo su vigencia hasta el 30 septiembre de 2031

La presente DJ será válida cuando sea escaneado su código QR y verificada digitalmente a través de la página de ANMAT. Asimismo, deberá estar acompañada de las disposiciones o DJ de habilitación enunciadas anteriormente.



La validez del presente documento deberá verificarse mediante el código QR.

N° Identificador Trámite: 81629

Tramitada por Expediente N°: 1-0047-3110-007221-26-3



FOENQUINOS Gerardo Ariel
CUIL 20233728897



VARELA Daniel Marcelo
CUIL 20927221617