

United States of America



DEPARTMENT OF STATE

To all to whom these presents shall come, Greetings:

I Certify That the document hereunto annexed is under the Seal of the District of Columbia, and that such Seal is entitled to full faith and credit.*

**For the contents of the annexed document, the Department assumes no responsibility.
This certificate is not valid if it is removed or altered in any way whatsoever*

In testimony whereof, I, Rex W. Tillerson, Secretary of State, have hereunto caused the seal of the Department of State to be affixed and my name subscribed by the Assistant Authentication Officer, of the said Department, at the city of Washington, in the District of Columbia, this twenty-sixth day of May, 2017.

Handwritten signature of Rex W. Tillerson in blue ink.

Secretary of State

By

Handwritten signature of Rex W. Tillerson in blue ink.

Assistant Authentication Officer,

Department of State

Đại sứ quán nước CHXHCN Việt Nam tại Hoa Kỳ
Embassy of the S.R of Vietnam in the United States of America

CHỨNG NHẬN / HỢP PHÁP HÒA LÃNH SỰ

CONSULAR AUTHENTICATION

Việt Nam

1. Quốc gia
Country

Giấy từ tài liệu này
This public document

2. do Ông (Bà)
has been signed by

Bộ trưởng ngoại giao

3. với chức danh
acting in the capacity of

Bộ Ngoại giao

4. và con dấu của
bears the seal/stamp of

Hợp chủng quốc Hoa Kỳ

được chứng nhận / hợp pháp hóa lãnh sự
Certified

5. tại Washington D.C. ngày 31/ 5/ 2017

at the

7. Cơ quan cấp Đại sứ quán Việt Nam tại Hoa Kỳ

8. Số
by 1771 / HP/H/2017

Ký tên và đóng dấu

Signature and seal/stamp

Tên họ

Nguyễn Tuấn



DECLARATION OF CONFORMITY

MANUFACTURER: NuVasive[®], Incorporated
7475 Lusk Blvd.
San Diego, CA 92121
United States of America
(858) 909-1800

EUROPEAN REPRESENTATIVE: NuVasive[®] UK Ltd.
Suite B,
Ground Floor
Caspian House
The Waterfront
Elstree, WD6 3BS
UK
+44 (0) 208 238 7850

PRODUCT: SpheRx[®] Spinal System Instruments (See Attached List)

CLASSIFICATION: Class I, Rule 6 according to Annex IX of the MDD

CONFORMITY ASSESSMENT ROUTE: Annex VII

We herewith declare that the abovementioned products meet the provisions of the Council Directive 93/42/EEC for medical devices. All supporting documentation is retained under the premises of the manufacturer.

STANDARDS APPLIED: ISO 13485: 2003

YEAR OF CE MARKING: 2005

ISSUED BY: NuVasive, Incorporated
7475 Lusk Boulevard
San Diego, California 92121
United States of America

PREPARED BY: 
Chris Reah
Specialist, Regulatory Affairs

21 DECEMBER 2014
Date

MANUFACTURER'S DECLARATION OF CONFORMITY

AUSTRALIAN THERAPEUTIC GOODS (MEDICAL DEVICES) REGULATIONS 2002

This is a declaration of conformity made under clause 6.6 of Schedule 3 to the Therapeutic Goods (Medical Devices) Regulations 2002.

FULL QUALITY ASSURANCE PROCEDURES

Manufacturer's Name: NuVasive[®], Incorporated

Business Address: 7475 Lusk Blvd
San Diego, CA 92121
United States of America
(858) 909-1800

Medical Device(s): See attached schedule

Classification: Class I - classification rule 3.2(4) of Schedule 2

GMDN Code and Term: 43257 Bone-screw internal spinal fixation system

Scope of Application: All

Each kind of medical device to which the system has been applied complies with the applicable provisions of the essential principles, the classification rules, and the full quality assurance procedures, at each stage, from the design of the device until its final inspection before being supplied.

Full quality assurance procedures certificate: ISO 13485 certificate: FM 93927

Standards Applied: ISO 13485: 2003

Year of CE Marking: 2005

Authorised Signatory:



Chris Reah
Specialist, Regulatory Affairs

2 SEPTEMBER 2014
Date

DECLARATION LIST TO DECLARATION OF CONFORMITY FOR SPHERON® SPINAL SYSTEM

Number	Part Description
1002174	RED VINYL END CAP FOR 3/4" TUBE
1006736	DEPTH GAUGE
1013137	OVERLAPPING SHIM
1014511	TAPERED BRACKET #1
1014512	TAPERED BRACKET 2
1014513	TAPERED BRACKET 3
1014514	XL BRACKET 1
1014515	XL BRACKET 2
1014516	XL BRACKET 3
1014517	SILICONE BAR HOLDER 2.25IN., TWO HOLE
1014518	SILICONE BAR HOLDER 2.38IN.
1014519	SILICONE BAR HOLDER 2.25IN., ONE HOLE
1015493	INSERT, 4-SCALLOP MOLDED
1542602	ANTERIOR COMPRESSOR ARM
1542603	ANTERIOR COMPRESSOR ARM
1590140	MAS PLIF Pin Mat, Fixation Implant Case
1599102	Generic Base, Sterilization Case
1599105	Pin mat
3400030	MAS ILLIF 1st DILATOR
3400035	MAS® TLIF Shankdriver, Posted
3400042	ROD MEASUREMENT TOOL
7070005	4.5mm Drill
7070006	5.0mm Drill
7070007	5.5mm Drill
7070009	6.5mm Drill
7070011	4.5mm 3Z Tap
7070012	5.0mm 3Z Tap
7070013	5.5mm 3Z Tap
7070015	6.5mm 3Z Tap
7070018	Shank Driver (Modular, neck)
7070020	Ratcheting Straight Handle, Long
7070021	Ratcheting Straight Handle, Jeweler's knob
7070035	Lateral Tulip Reamer
7070036	Tulip Reamer
7070039	Drill Guide
7070041	Counter Torque
7070042	Drill/Tap Insulator
7070044	Guide Insulator
7070046	Driver Insulator
7070047	MAS PLIF Hemostat Rod Insertor
7070048	Reducer Knob
7070051	Reducer
7070052	Screwdriver (Assembled)
7070053	Rod Measurement Tool
7070054	Head Insertor
7070055	Verification Torque T-Handle, MAS-PLIF
7070056	MAS PLIF Lock Screw Starter, Expandable
7070057	MAS PLIF Driver, Lock Screw
7070103	Instrument Bottom Tray
7070104	Instrument Middle Tray
7070105	Instrument Top Tray
7070107	MAS PLIF Fixation Implant Case Base
7070108	MAS PLIF Fixation Implant Bottom Tray
7070109	MAS PLIF Fixation Implant Top Tray
7070110	MAS PLIF Screw Assembly Loading Block
7070111	MAS PLIF Tulip Caddy
7070112	MAS PLIF Tulip Caddy Lid
7070113	MAS PLIF Shank Caddy
7070114	MAS PLIF Shank Caddy Lid
7070115	Screw Assembly Caddy
7070116	Screw Assembly Caddy Lid
7070117	MAS PLIF Lock Screw Caddy
7070118	MAS PLIF Lock Screw Caddy Lid

ATTACHED LIST TO DECLARATION OF CONFORMITY FOR SPHERX® SPINAL SYSTEM

Number	Part Description
7070119	Instrument Case Placard Small
7070120	Implant Case Placard Small
7070121	Instrument Case Placard Large
7070122	Implant Case Placard Large
7100125	TLIF Distractor, Size 10-19mm
7100126	TLIF Distractor, Size 10-24mm
7100127	TLIF Distractor, Size 10-29mm
7100128	TLIF Distractor, Size 10-34mm
7100129	TLIF Distractor, Size 10-39mm
7100132	TLIF Distractor Removal Tool
7100133	Measurement Tool, TLIF Distractor
7100134	TLIF Distractor Insert
7100135	3.5mm Tapered Hex Driver
7100136	Detachable Driver-Quick Connect
7101535	5.5mm x 35mm Detachable Tap
7101545	5.5mm x 45mm Detachable Tap
7101635	6.5mm x 35mm Detachable Tap
7101645	6.5mm x 45mm Detachable Tap
7104535	4.5mm x 35mm Self-Tapping Screw
7104545	4.5mm x 45mm Self-Tapping Screw
7190001	SPHERX® II DOUBLE LEAD SCREW TRAY, BASE
7190003	SPHERX® II DOUBLE LEAD SCREW TRAY, LID
7190045	SPHERX® II DOUBLE LEAD TAP 1533791
7190055	SPHERX® II DOUBLE LEAD TAP 1533796
7190065	SPHERX® II DOUBLE LEAD TAP 1533797
7190075	SPHERX® II DOUBLE LEAD TAP 1533798
7200001	SPHERX® TRAY 1
7200002	SPHERX® TRAY 2
7200004	8.5MM FIXED AXIS SCREW TRAY BASE
7200005	SPHERX® II HOOK/FIXED SCREW TRAY, BASE
7200006	STERILIZATION CASE SPHERX® 4.5MM SCREWS
7200007	8.5MM FIXED AXIS SCREW TRAY LID
7200008	STERILIZATION CASE SPHERX® TRAY 1
7200009	STERILIZATION CASE SPHERX® TRAY 2
7200010	IMPLANT TRAY 3
7200011	4.5MM SCREW TRAY, BASE
7200012	STERILIZATION CASE SPHERX® PRE-BENT RODS
7200013	4.5MM SCREW TRAY, LID
7200014	SPHERX® PRE-BENT ROD TRAY, BASE
7200015	SPHERX® PRE-BENT ROD TRAY, LID
7200016	SPHERX® INSTRUMENT TRAY 1, BASE
7200017	SPHERX® INSTRUMENT TRAY 1, INSERT
7200018	SPHERX® LID
7200019	T-HANDLE W/O RATCHET MECHANISM
7200020	DRIVER HANDLE STRAIGHT W/O RATCHET
7200021	SPHERX® INSTRUMENT TRAY 2, BASE
7200022	SPHERX® INSTRUMENT TRAY 2, INSERT
7200023	AWL
7200024	SPHERX® IMPLANT TRAY, BASE
7200025	SPHERX® IMPLANT TRAY, INSERT
7200026	DRIVER HANDLE, STRAIGHT
7200027	T-HANDLE
7200028	Ball-tip Probe
7200029	BALL-TIP PEDICLE PROBE, CURVED
7200030	Depth Gauge
7200031	DBR® ROD HOLDER
7200032	ROD HOLDER, STRAIGHT
7200033	ROD HOLDER, ANGLED
7200034	ROD GRIPPER
7200035	ROD BENDER
7200036	ROD PUSHER
7200037	ROD FORK
7200038	SPHERX® HEAD ADJUSTER

ATTACHED LIST TO DECLARATION OF CONFORMITY FOR SPHERX® SPINAL SYSTEM

Number	Part Description
7200039	LOCK SCREW DRIVER
7200040	ANTI TORQUE TOOL
7200041	TORQUE T-HANDLE
7200042	COMPRESSOR
7200043	SPHERX® LOCK SCREW CADDY
7200044	TRANSVERSE CONNECTOR HOLDER
7200045	TRANSVERSE CONNECTOR SCREWDRIVER
7200046	SPHERX® TRANSVERSE CONNECTOR CADDY
7200048	Rod Cutter
7200049	CALIPER
7200050	TORQUE DRIVER
7200051	GEARSHIFT PROBE, STRAIGHT
7200052	GEARSHIFT PROBE, CURVED
7200060	SCREW DRIVER II
7200061	SCREWDRIVER III
7200064	SCREWDRIVER III WITH JACOBS CHUCK END
7200065	LOCK SCREW GUIDE
7200066	LOCK SCREW STARTER
7200075	DISTRATOR/COMPRESSOR TIP, SPHERICAL
7200076	DISTRATOR/COMPRESSOR TIP STANDARD RIGHT
7200077	DISTRATOR/COMPRESSOR TIP, STANDARD LEFT
7200080	DISTRATOR
7200081	DISTRATOR/COMPRESSOR TIP, HOOK RIGHT
7200082	DISTRATOR/COMPRESSOR TIP, HOOK LEFT
7200083	DISTRATOR OFFSET TIP, RIGHT
7200084	DISTRATOR OFFSET TIP, LEFT
7200085	COMPRESSOR OFFSET TIP, LEFT
7200086	COMPRESSOR OFFSET TIP, RIGHT
7200087	DISTRATOR/COMPRESSOR STRAIGHT HOOK, RT
7200088	DISTRATOR/COMPRESSOR STRAIGHT HOOK, LT
7200095	PERSUADER
7200096	PERSUADER LOCK SCREW DRIVER
7200098	STERILIZATION CASE SPHERX® PERSUADER
7201035	CANNULATED DRILL, °3.5MM
7201040	CANNULATED DRILL, °4.0MM
7201145	4.5MM CANNULATED TAP
7201155	5.5MM CANNULATED TAP
7201165	6.5MM CANNULATED TAP
7201175	7.5MM CANNULATED TAP
7201245	CANNULATED FLUTED TAP, °4.5MM
7201255	CANNULATED FLUTED TAP, °5.5MM
7201265	CANNULATED FLUTED TAP, °6.5MM
7201275	CANNULATED FLUTED TAP, °7.5MM
7201345	NON - CANNULATED FLUTED TAP, 4.5MM
7201355	NON-CANNULATED FLUTED TPA, 5.5MM
7201365	NON-CANNULATED FLUTED TAP, 6.5MM
7201375	NON-CANNULATED FLUTED TAP, 7.5MM
7201445	4.5 MM TAP
7201455	.5 MM TAP
7201465	6.5 MM TAP
7201475	7.5 MM TAP
7201485	8.5MM TAP
7210031	Primary Insulator
7210032	SECONDARY INSULATOR
7210033	THIRD INSULATOR
7228599	NUVASIVE® SCREW CASE
7230001	SPHERX® DBR® INSTRUMENT TRAY, BASE
7230002	SPHERX® DBR® INSTRUMENT TRAY, INSERT
7230003	SPHERX® DBR® LID
7230004	SPHERX® DBR® IMPLANT TRAY, BASE
7230005	SPHERX® DBR® IMPLANT TRAY, ROD INSERT BA
7230006	SPHERX® DBR® IMPL TRAY- ROD INSERT MIDDLE
7230007	SPHERX® DBR® IMPLANT TRAY, ROD INSERT TO

ATTACHED LIST TO DECLARATION OF CONFORMITY FOR SPHERX® SPINAL SYSTEM

Number	Part Description
7230010	DBR® INSTRUMENT TRAY
7230011	STER CASE SPHERX® DBR® SUPPLEMENTAL RODS
7230015	DBR® IMPLANT TRAY
7230023	Cannulated Awl
7230030	DBR® FIXED HANDLE
7230031	FIXED HANDLE, SMALL W/ RATCHET MECHANISM
7230045	DBR® - CANNULATED FLUTED TAP, 4.5MM
7230055	DBR® - CANNULATED FLUTED TAP, 5.5MM
7230065	DBR® CANNULATED FLUTED TAP, 6.5MM
7230075	DBR® CANNULATED FLUTED TAP, 7.5MM
7230100	DUAL BALL ROD GUIDE
7230110	DUAL BALL ROD SCREWDRIVER SLEEVE
7230111	DBR® - SCREWDRIVER SHAFT
7230115	DBR® REATTACHMENT TOOL
7230117	DBR® - BLUNT DISSECTOR
7230120	DBR® ROD MEASUREMENT TOOL
7230125	DBR® ROD PUSHER
7230130	DBR® LOCK SCREW DRIVER
7230135	DBR® COUNTER TORQUE TOOL
7230141	DBR® Tap Insulator
7230142	DBR® SCREW INSULATOR
7230200	SPLIT DBR® GUIDE
7230205	DBR® COUNTER-TORQUE TUBE
7231045	4.5 MM CANNULATED TAP
7231055	5.5 MM CANNULATED TAP
7231065	6.5 MM CANNULATED TAP
7231075	7.5 MM CANNULATED TAP
7240001	SPHERX® II INSTRUMENT TRAY 1
7240002	SPHERX® II INSTRUMENT TRAY 2
7240003	SPHERX® II IMPLANT TRAY
7240004	SPHERX® II HOOK/FIXED SCREW TRAY
7240005	SPHERX® II CONVENTIONAL ROD TRAY
7240006	SPHERX® II HOOK/FIXED SCREW TRAY, INSERT
7240008	SpheRx II Instrument Tray 2 Top
7240009	SpheRx II Instrument Tray 2 Middle
7240010	Quick Connect Straight Handle
7240011	STRAIGHT GEARSHIFT PROBE
7240012	Curved Gearshift Probe
7240013	Lock Screw Starter
7240014	ROCKER
7240015	CROSS CONNECTOR HOLDER
7240016	CROSS CONNECTOR SCREWDRIVER
7240018	HOOK TRIALS
7240019	COMPRESSOR
7240020	DISTRACTOR/TC LOCK RING DRIVER
7240021	ANGLED ROD HOLDER
7240022	ROD GRIPPER
7240023	ROD PUSHER
7240024	COUNTER TORQUE
7240025	Torque T-Handle
7240026	CROSS CONNECTOR MEASUREMENT GUIDE
7240027	TAP INSULATOR
7240028	SCREW INSULATOR
7240029	PEDICLE MARKER, SPHERICAL
7240030	PEDICLE MARKER, DIAMOND
7240031	IMPLANT HOLDER
7240032	REDUCER
7240033	ROD TEMPLATE, 250MM
7240034	ROD TEMPLATE, 500MM
7240035	LATERAL PERSUADER
7240036	IN-SITU BENDER, RIGHT
7240037	SELF-RETAINING SCREWDRIVER
7240038	POLYAXIAL SCREWDRIVER

APPENDIX A - ATTACHED LIST TO DECLARATION OF CONFORMITY FOR SPHERX® SPINAL SYSTEM

Number	Part Description
7240039	SCREW ADJUSTER
7240040	Lock Screw Driver
7240041	Quick Connect T-Handle
7240042	AWL
7240043	NARROW AWL
7240044	CROSS CONNECTOR BENDER, LEFT
7240045	CROSS CONNECTOR BENDER, RIGHT
7240046	ROD ROTATION WRENCH
7240047	NARROW GEARSHIFT PROBE, STRAIGHT
7240048	GRIP REDUCER
7240049	REDUCER LOCK SCREW DRIVER
7240050	SCREW HEAD ADJUSTER
7240051	LOCK SCREW STARTER GUIDE
7240052	HOOK PUSHER
7240053	LAMINA ELEVATOR
7240054	TRANSVERSE PROCESS ELEVATOR
7240055	HOOK INSERTER
7240056	FIXED HEAD SCREWDRIVER
7240057	ROD CONNECTOR DRIVER
7240058	CROSS CONNECTOR LOCK RING DRIVER
7240059	NARROW GEARSHIFT PROBE, CURVED
7240060	PEDICLE ELEVATOR
7240061	FORK ROCKER
7240062	STRAIGHT ROD HOLDER
7240063	LOCK SCREW STARTER, STRAIGHT
7240064	SPHERX® II STERILIZATION CASE 1, BASE
7240065	SPHERX® II STER CASE 1, MIDDLE INSERT
7240066	SPHERX® II STER CASE 1, TOP INSERT
7240067	SPHERX® II STERILIZATION CASE 2, BASE
7240068	SPHERX® II STER CASE 2, MIDDLE INSERT
7240069	SPHERX® II STER CASE 2, TOP INSERT
7240070	SPHERX® II STERILIZATION CASE 3, BASE
7240071	SPHERX® II STER CASE 3, MIDDLE INSERT
7240072	SPHERX® II STER CASE 3, TOP INSERT
7240073	SPHERX® II STERILIZATION CASE LID
7240074	SPHERX® II ROD BENDER
7240075	IN-SITU BENDER, LEFT
7240076	1/4" SQUARE/JACOBS CHUCK ADAPTER
7240077	SPHERX® II TRANSVERSE CONNECTOR CADDY
7240078	SPHERX® II LOCK SCREW CADDY
7240079	TRANSVERSE CONNECTOR DRIVER
7240080	TRANSVERSE CONNECTOR TORQUE T-HANDLE
7240081	VARIABLE TRANSVERSE CONNECTOR CADDY
7240082	VARIABLE TRANSVERSE CONNECTOR CADDY LID
7240083	VARIABLE TRANSVERSE CONNECTOR TRAY INSRT
7240084	SPII TRANSVERSE CONNECTOR TORQUE T-HANDL
7240085	SPHERX® II REDUCTION SCREWDRIVER
7240086	REDUCTION COUNTER TORQUE
7240087	REDUCTION SCREW BREAKOFF TOOL
7240089	SPHERX® II REDUCTION SCREW TRAY BASE
7240090	SPHERX® II REDUCTION SCREW TRAY CADDY
7240091	SPHERX® II REDUCTION SCREW TRAY NIPPLE M
7240092	POLYAXIAL SCREWDRIVER DISMANTLABLE
7240099	SpheRx® II Pin Mat
7240100	SpheRx® II Caddy, Lock Screw
7240102	SpheRx® II Conventional Rod Case
7240104	SpheRx II Instrument Tray 1 Top
7240105	SpheRx II Instrument Tray 1 Middle
7240106	SpheRx II Instrument Tray 1 Base
7240108	SpheRx II Hook/Fixed Screw Tray Level 1
7240109	SpheRx II Hook/Fixed Screw Tray Caddy 1
7240110	SpheRx II Hook/Fixed Screw Tray Caddy 2
7240111	SpheRx II Hook/Fixed Screw Tray Base

INDEXED LIST TO DECLARATION OF CONFORMITY FOR SPHERX® SPINAL SYSTEM

Number	Part Description
7240112	SpheRx® II Instrument Tray 2 Base
7240145	4.5MM TAP
7240155	5.5MM TAP
7240165	6.5MM TAP
7240175	7.5MM TAP
7240180	SpheRx® II Base, Implant Tray
7240181	SpheRx® II Top, Implant Tray
7240185	8.5MM TAP
7240200	SpheRx® II Caddy, Screw
7241040	ADJUSTABLE TRANSVERSE CONNECTOR, 40-49M
7247001	SpheRx® II MAS Screwdriver
7247002	SpheRx® II MAS Compressor
7247003	SpheRx® II MAS Distractor
7247004	SpheRx® II MAS Rod Holder
7247005	SpheRx® II MAS Persuader
7247006	SpheRx® II MAS Counter Torque
7247007	SPHERX® II MAS INSTRUMENT TRAY
7247008	SpheRx® II MAS Instrument Tray, Base
7247009	SpheRx® II MAS Instrument Tray, Insert
7247010	SpheRx® II MAS Tray/TLIF Distractor Set
7247011	SpheRx® II MAS Tray, Distractor Caddy L
7247012	SpheRx® II MAS Instrument Tray, Lid
7249000	SPHERX® II ILIAC SCREW TRAY
7249001	SPHERX® II ILIAC SCREW TRAY LID
7249002	SPHERX® II ILIAC SCREW TRAY BASE
7249003	SPHERX® II ILIAC SCREW TRAY INSERT
7250001	S II ANT SYS INSTRUMENT TRAY I - BASE
7250002	S II ANT SYS INSTRUMENT TRAY I - MIDDLE
7250003	S II ANT SYS INSTRUMENT TRAY I - TOP
7250004	S II ANT SYS INSTRUMENT TRAY II - BASE
7250005	S II ANT SYS INSTRUMENT TRAY II-MIDDLE
7250006	S II ANT SYS INSTRUMENT TRAY II - TOP
7250007	S II ANT SYS IMPLANT TRAY - BASE
7250008	S II ANT SYS IMPLANT TRAY - INSERT
7250009	S II ANT SYS TRAY - LID
7250010	S II ANT SYS FIXED CONNECTOR CADDY
7250011	S II ANT SYS FIXED CONNECTOR CADDY-LID
7250021	ANGLED AWL
7250022	SELF-CENTERING AWL
7250023	DRILL, 3.5MM
7250024	ANGLED DRILL, 3.5MM
7250026	DEPTH MEASUREMENT TOOL
7250027	FIXED SCREW DRIVER
7250028	ANGLED FIXED SCREW DRIVER
7250029	ANGLED POLYAXIAL SCREW DRIVER
7250031	ROD PUSHER
7250032	COMPRESSOR
7250033	DISTRACTOR
7250034	RACK COMPRESSOR
7250036	LOCK SCREW STARTER GUIDE/COUNTER TORQUE
7250037	STAPLE INSERTER
7250038	STAPLE INSERTER RETAINER
7250039	SINGLE-HOLE STAPLE INSERTER
7250042	STAPLE GUIDE HANDLE
7250043	STAPLE GUIDE HANDLE RETAINER
7250051	FIXED CONNECTOR TEMPLATE, 15MM - 16MM
7250052	FIXED CONNECTOR TEMPLATE, 17MM - 18MM
7250053	FIXED CONNECTOR TEMPLATE, 19MM - 20MM
7250054	FIXED CONNECTOR TEMPLATE, 21MM - 22MM
7250056	FIXED CONNECTOR TORQUE T-HANDLE
7250062	SCREW ADJUSTER
7250063	LOCK SCREW DRIVER
7250064	LOCKSCREW STARTER

ATTACHED LIST TO DECLARATION OF CONFORMITY FOR SPHERX® SPINAL SYSTEM

Part Number	Part Description
7250066	SPHERX® II ANTERIOR AWL
7250067	SPHERX® II ANTERIOR ANGLED AWL
7250068	SELF-CENTERING AWL
7250069	SPHERX® II ANTERIOR LONG AWL
7250070	DRILL, 3.5MM
7250072	GUIDE SLEEVE
7250073	SPHERX® II ANTERIOR DEPTH MEASUREMENT TO
7250074	SPHERX® II ANTERIOR FIXED SCREWDRIVER
7250077	SPHERX® II ANTERIOR PIVOTING ROD HOLDER
7250078	SPHERX® II ANTERIOR ROD PUSHER
7250079	SPHERX® II ANTERIOR COMPRESSOR
7250080	SPHERX® II ANTERIOR DISTRACTOR
7250081	SPHERX® II ANTERIOR COUNTER TORQUE
7250082	SPHERX® II ANTERIOR FINAL DRIVER
7250083	STAPLE INSERTER
7250084	ANTERIOR GUIDE RETAINER
7250088	FLEX LOCK SCREW STARTER
7250089	ANTERIOR CROSS CONNECT TEMPLATE
7250091	ANTERIOR CROSS CONNECT TEMPLATE
7250092	ANTERIOR CROSS CONNECT TEMPLATE
7250093	ANTERIOR CROSS CONNECT TEMPLATE
7250094	ANTERIOR CROSS CONNECT TEMPLATE
7250095	SPHERX® II ANTERIOR STAPLE TAMP
7250097	TEMPORARY PIN INSERTER
7250099	COMPRESSOR BLOCK
7250100	ANTERIOR CROSS CONNECT TEMPLATE
7250101	ANTERIOR CROSS CONNECT TEMPLATE
7250102	ANTERIOR CROSS CONNECT TEMPLATE
7250103	ANTERIOR CROSS CONNECT TEMPLATE
7250105	ANTERIOR CROSS CONNECT DRIVER
7250106	DBR COUNTER-TORQUE TOOL
7250107	CROSS CONNECT INSERTER
7250108	SPHERX II ANTERIOR COMPRESSOR TIPS
7250109	SPHERX® II ANTERIOR DISTRACTOR TIPS
7250110	SPHERX® II ANTERIOR COMPRESSOR/DISTRACTO
7250111	SPHERX® II ANTERIOR INSTRUMENT TRAY 1
7250112	SPHERX® II ANTERIOR INSTRUMENT TRAY 2
7250113	SPHERX II ANTERIOR IMPLANT TRAY
7250114	SPII ANTERIOR STAPLE CADDY
7250115	SPII ANTERIOR STAPLE CADDY LID
7250116	SPII ANTERIOR SINGLE HOLE STAPLE CADDY
7250117	SPII ANTERIOR SINGLE HOLE STAPLE CADDY L
7250118	SPII ANTERIOR WASHER CADDY
7250119	SPII ANTERIOR WASHER CADDY LID
7250120	SPII ANTERIOR CROSS CONNECT CADDY
7250121	SPII ANTERIOR CROSS CONNECT CADDY LID
7250122	SPII ANTERIOR LOCKSCREW CADDY
7250123	SPII ANTERIOR LOCKSCREW CADDY LID
7250124	SPII ANTERIOR POLYAXIAL SCREW CADDY
7250125	SPII ANTERIOR FIXED SCREW CADDY
7250126	SPII ANTERIOR TRAY LID
7250127	SPII ANTERIOR IMPLANT TRAY INSERT 1
7250128	SPII ANTERIOR IMPLANT TRAY INSERT 2
7250129	SPII ANTERIOR IMPLANT TRAY BASE
7250130	SPII ANTERIOR INSTRUMENT TRAY 1 INSERT 1
7250131	SPII ANTERIOR INSTRUMENT TRAY 1 INSERT 2
7250132	SPII ANTERIOR INSTRUMENT TRAY 1 BASE
7250133	SPII ANTERIOR INSTRUMENT TRAY 2 INSERT 1
7250134	SPII ANTERIOR INSTRUMENT TRAY 2 INSERT 2
7250135	SPII ANTERIOR INSTRUMENT TRAY 2 BASE
7250155	TAP, 5.5MM
7250165	TAP, 6.5MM
7250175	TAP, 7.5MM

APPENDIX A - ATTACHED LIST TO DECLARATION OF CONFORMITY FOR SPHERX® SPINAL SYSTEM

Part Number	Part Description
7250255	ANGLED TAP, 5.5MM
7250265	ANGLED TAP, 6.5MM
7250275	ANGLED TAP, 7.5MM
7250345	ANTERIOR TAP
7250355	ANTERIOR TAP
7250365	ANTERIOR TAP
7250375	ANTERIOR TAP
7250526	INFERIOR STAPLE GUIDE, SMALL
7250528	INFERIOR STAPLE GUIDE, MEDIUM
7250530	INFERIOR STAPLE GUIDE, LARGE
7250626	SUPERIOR STAPLE GUIDE, SMALL
7250628	SUPERIOR STAPLE GUIDE, MEDIUM
7250630	SUPERIOR STAPLE GUIDE, LARGE
7255026	STAPLE GUIDE - SM - SUP
7255028	STAPLE GUIDE - MD - SUP
7255030	STAPLE GUIDE - LG - SUP
7255126	STAPLE GUIDE - SM - INF
7255128	STAPLE GUIDE - MD - INF
7255130	STAPLE GUIDE - LG - INF
7270001	SpheRx® DBR® II Instrument Tray
7270002	SPHERX® DBR® II IMPLANT TRAY
7270003	DBR® II Alternate Rod Delivery Tray
7270010	DBR® II Counter-Torque/Reduction Tube
7270011	DBR® II Reduction T-Handle
7270012	DBR® II Counter-Torque Tool
7270013	DBR® II Guide
7270014	DBR® II Reduction Extension
7270015	Split DBR® II Non-Locking Guide
7270016	DBR® II Rod Pusher
7270017	DBR® II Tissue Dissector
7270018	DBR® II Alternate Rod Inserter
7270019	DBR® II Screwdriver
7270020	DBR® II Rod Measurement Tool
7270021	DBR® II Lock Screw Driver
7270022	DBR® II Lock Screw Starter
7270023	Primary Insulator
7270024	Tap Insulator
7270025	Screw Insulator
7270026	DBR® II ROD DELIVERY TEMPLATE
7270027	K-Wire Driver
7270028	DBR® II SCREW ALIGNMENT GUIDE
7270029	DBR® II Re-attachment tool
7270030	DBR® II Sphere Gripper
7270031	DBR® II Non-Locking Guide
7270032	Ratcheting Teardrop Handle
7270033	DBR® II ROD HOLDER
7270034	DBR® Self-Retaining Screwdriver
7270035	DBR® II Alternate Delivery Guide
7270036	NON-RATCHETING TEARDROP HANDLE
7270037	TECASON P XRO: GREY
7270038	TECASON P XRO: PURPLE
7270039	TECASON P XRO: BLACK
7270040	Curved Tissue Dissector
7270041	DBR® II ALTERNATE DELIVERY GUIDE RING
7270042	SPHERX® DBR® II THUMB SCREW
7270043	Threaded Rod Pusher
7270044	Counter-Torque Wrench
7270045	Alternate Rod Pusher
7270046	Non Locking Alternate Guide
7270047	NEW SPHERE GRIPPER
7270048	Rod Retrieval Tool
7270049	Quick-Connect Straight Handle, Short
7270050	Sphere Gripper, 30 Degree

ATTACHED LIST TO DECLARATION OF CONFORMITY FOR SPHERx® SPINAL SYSTEM

Part Number	Part Description
7270051	Sphere Gripper, 60 Degree
7270052	INSULATOR PUSHER
7270053	COMPRESSOR DISTRACTOR HANDLE
7270054	DBR® II Compressor Arm, Short
7270055	DBR® II Compressor Arm, Long
7270056	DBR® II Compressor Rack
7270057	DBR® II Cannulated Awl
7270058	DBR® II Rod Holder
7270059	DBR® II Single Level Reducer
7270060	DBR® II Single Level Reducer Cap
7270061	CONSTRAINED ROD PUSHER
7270065	DBR® II DISTRACTOR RACK
7270066	DBR® II DISTRACTOR EXTENSIONS
7270070	DBR® II MAS SCREWDRIVER
7270072	DBR II 90 DEG 6.25MM ROD INSE
7270073	DBR II 90 DEGREE INSERTER
7270074	DBR II INSERTER DRIVER
7270080	EXPANDABLE LOCKSCREW STARTER
7270082	DBR II INSERTER DRIVER
7270101	SpheRx® DBR® II Tray 1, Base
7270145	4.5mm Cannulated Tap
7270155	5.5mm Cannulated Tap
7270165	6.5mm Cannulated Tap
7270175	7.5mm Cannulated Tap
7270203	SpheRx® DBR® II Tray 2, Base
7270301	SpheRx® DBR® II Tray 1, Top Insert
7270303	SpheRx® DBR® II Tray 2, Top Insert
7270401	SpheRx® DBR® II Tray 1, Mid Insert
7270403	SpheRx DBR II Tray 2 Bottom Insert
7270404	DBR II Inserter Insert
7280102	SpheRx DBR III Implant Base
7280103	DBR III MOD Implant/Instrument Tray Base
7280104	DBR III MOD Cannulated Screw Caddy
7280105	DBR III MOD Lock Screw Caddy
7280106	DBR III MOD Tulip Caddy
7280107	DBR III MOD Tulip Caddy Lid
7280108	DBR III MOD Lock Screw Caddy Lid
7280109	DBR III MOD Top Tray
7280110	DBR III MOD Middle Tray
7280111	DBR III MOD Bottom Tray
7280202	SpheRx DBR III Implant Tray Top Insert
7280302	NuVasive Tray Lid
7280402	SpheRx DBR III Implant Bottom Insert
7280502	SpheRx DBR III Lock Screw Caddy
7280602	SpheRx DBR III Lock Screw Caddy Lid
7280702	SpheRx DBR III Screw Caddy
7281111	DBR®III Instrument Tray 2, Top
7281112	DBR®III Instrument Tray 2, Base
7281113	DBR®III Instrument Tray 2, Bottom Level
7281114	DBR®III Insert, Rod Inserter Tray 2
7281116	DBR®III Instrument Tray 1, Top
7281117	DBR®III Instrument Tray 1, Middle
7281118	DBR®III Instrument Tray 1, Bottom
7281119	DBR® III MOD Caddy, Shank
7281121	DBR® III MOD Tag, Large
7281122	DBR® III MOD Tag, Small
7281128	DBR®III Tray Base, Modular
7290055	DOUBLE-LEAD TAP, 5.5MM
7290065	DOUBLE-LEAD TAP, 6.5MM
7290075	DOUBLE-LEAD TAP, 7.5MM
7290085	DOUBLE-LEAD TAP, 8.5MM
7451001	Awl
7451106	REDUCTION COUNTER TORQUE

ATTACHED LIST TO DECLARATION OF CONFORMITY FOR SPHERX® SPINAL SYSTEM

Part Number	Part Description
7459003	Gearshift Probe
7459007	Ball-Tip Probe
7459451	SpheRx® PPS Base, Instrument Case
7459452	SpheRx® PPS Bottom, Instrument Case
7459453	SpheRx® PPS Middle, Instrument Case
7459454	SpheRx® PPS Top, Instrument Case
7770021	PPS Tray Lid
7770023	SPX PPS Tray 6.25 Tulip/LS Caddy
7770024	PPS Screw Caddy
7770026	SPX PPS Tray Distractor Caddy
7770033	SPX PPS Tray 6.25 Tulip Caddy Lid
7770034	SPX PPS Tray 6.25 Lock Screw Caddy Lid
7770035	SPX PPS Tray Distractor Caddy Lid
7770037	SPX PPS Tray Protective Sleeve Caddy
7770040	SPX PPS Tray Protective Sleeve Caddy Lid
7770050	5.5mm Base Tray
7770051	SPX PPS Tray Inst/Imp Top Level Insert
7770052	SPX PPS Tray Inst/Imp Middle Insert
7770053	SPX PPS Tray 6.25 Inst/Imp Base
7770054	SPX PPS Pre-Assembly Loading Block
7770056	SPX PPS Open Instrument Tray Base
7771116	Compressor
7771155	6.25MM PPS THREADED PUSHER
7771157	Distractor Inserter
7771160	SCREW HEAD ADJUSTER 6.25MM ROD
7771161	SCREW ADJUSTER
7771163	ASSEMBLED PPS DRIVER 6.25MM
7771164	TULIP REAMER
7771165	LATERAL TULIP REAMER
7771166	POSTED SHANKDRIVER
7771167	SELF-RETAINING SHANKDRIVER
7771169	VERIFICATION TORQUE T-HANDLE
7771172	HEAD INSERTER INSULATOR
7771173	PPS Distractor
7771174	PPS Protective Sleeve
7771175	POLYAXIAL HEAD INSERTER 6.25MM
7771176	PRE-ASSEMBLY VERIFICATION TOOL
7771177	Counter Torque
7771220	Distractor (10mm-20mm)
7771230	Distractor (10mm-30mm)
7771240	Distractor (10mm-40mm)
7772005	6.25mm Reduction Tulip
7772065	PPS Reduction Tower
7781155	5.5mm Threaded Rod Pusher
7781160	5.5mm Head Adjuster
7781163	Pre-Assembled Screwdriver
7781175	5.5mm Polyaxial Head Inserter
7781188	PPS Cannulated Screw Caddy, Lid
7782005	5.5mm Rod Inserter
7782006	5.5mm Rod Inserter Driver
7782008	5.5mm Rod Measurement Tool
7782009	5.5mm Rod Pusher
7782010	5.5mm Rod Holder
7782011	5.5mm Reattachment Tool
7782012	5.5mm Tulip/Lock Screw Caddy
7782205	Reduction Counter Torque
7782206	5.5mm Reduction Head Inserter
7782207	6.25mm Reduction Head Inserter
7782208	5.5mm Breakoff Tool
7782209	6.25mm Breakoff Tool
7782211	Screw Adjuster
7782212	5.5mm Pre-assembled Reduction Driver
7782213	6.25mm Pre-assembled Reduction Driver



ATTACHED LIST TO DECLARATION OF CONFORMITY FOR SPHERX® SPINAL SYSTEM

Part Number	Part Description
7783004	5.5mm Reduction Tulip
7785050	5.5mm Instrument Tray Base
7785051	5.5mm Instrument Tray Lid
7785052	5.5mm Instrument Top Tray
7785053	5.5mm Instrument Rod Insert
7785054	5.5mm Instrument Bottom Tray Insert
7785060	5.5mm Implant Tray Lid
7785061	5.5mm Implant Top Tray
7785062	5.5mm Implant Tray Base
7789001	Tulip Caddy Base
7789002	Tulip Caddy Lid
7789003	Base Tray
7789004	Large Tray Tag - 5.5mm
7789005	Small Tray Tag - 5.5mm
7789006	Large Tray Tag - 6.25mm
7789007	Small Tray Tag - 6.25mm
7791000	PPs Dual Hinged Distractor Rack
7791001	5.5mm Tulip Distractor Tip
7791002	Hoop Distractor Tip, Right
7791003	Hoop Distractor Tip, Left
7791004	Half Moon Distractor Tip, Right
7791005	Half Moon Distractor Tip, Left
8801021	Ratcheting Teardrop Handle
8801026	French Bender
8801057	Torque Handle
8801083	Rod Insert, Wiltze
8801222	Screw Adjuster
8801300	Generic NuVasive Tray Lid
8801333	Generic NuVasive Tray Lid
D3400035	MAS TLIF Shank Driver, Dismantlable
D7241048	Dismantlable SpheRx II Reduction Tower