

17028358-13

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 Secretary of State of the State(s) of Maryland, and that such Seal(s) is/are 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 twelfth day of April, 2017.

Rex W. Tillerson

Secretary of State

B. M. Allen

Issued pursuant to CHXIV, State of
Sept. 15, 1789, 1 Stat. 68-69; 22
USC 2657; 22USC 2651a; 5 USC



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 HÓA LÃNH SỰ
CONSULAR AUTHENTICATION

1. Quốc gia.....Việt Nam.....
Country
Giấy tờ, tài liệu này
This public document
2. do Ông (Bà)Rex W. Tillerson..... ký
has been signed by
3. với chức danhBộ trưởng ngoại giao.....
acting in the capacity of
4. và con dấu củaBộ Ngoại giao.....
bears the seal/stamp of
-Hợp chủng quốc Hoa Kỳ.....
được chứng nhận / hợp pháp hóa lãnh sự
Certified
5. tạiWashington D.C..... 6. ngày14/ 4/ 2017.....
at the
7. Cơ quan cấpĐại sứ quán Việt Nam tại Hoa Kỳ.....
by
8. Số1193 / HPH/2017
No

Ký tên và đóng dấu
Signature and seal/stamp

Tham tán

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:

Precept Spinal System (See Attached List)

CLASSIFICATION:

Class I, Rule 1 according to Annex IX of the MDD

**CONFORMITY ASSESSMENT
ROUTE:**

Annex II, Section 3

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

NOTIFIED BODY:

BSI Healthcare (ID #0086)
Kitemark Court,
Davy Avenue,
Knowlhill, Milton Keynes,
MK5 8PP, United Kingdom

YEAR OF CE MARKING:

2015

EC CERTIFICATE NUMBER

CE 96026

ISSUED BY:

NuVasive®, Incorporated
7475 Lusk Boulevard
San Diego, California 92121
United States of America

**PREPARED BY:**

Jeremy Markovich

17 DECEMBER 2015
Date

Associate Manager, Regulatory Affairs

MANUFACTURER'S DECLARATION OF CONFORMITY

AUSTRALIAN THERAPEUTIC GOODS (MEDICAL DEVICES) REGULATIONS 2002

This is a declaration of conformity made under clause 1.8 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 2.1 of Schedule 2

GMDN Code and Term: 44065 Neurosurgical procedure kit; non-medicated, reusable

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.

Notified Body: BSI Healthcare (ID #0086)
Kitemark Court,
Davy Avenue,
Knowlhill, Milton Keynes,
MK5 8PP, United Kingdom

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

Design examination certificate (if applicable): EC certificate number: CE 96026

Standards Applied: ISO 13485: 2003

Year of CE Marking: 2015

Authorised Signatory:



Jeremy Markovich

17 DECEMBER 2015
Date



Associate Manager, Regulatory Affairs

Attached List to Declaration of Conformity for Precept Spinal System	
Part Number	Part Description
8801026	PRECEPT French Bender

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: **Precept Spinal System (See Attached List)**

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

CONFORMITY ASSESSMENT ROUTE: Annex II, Section 3

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

NOTIFIED BODY: BSI Healthcare (ID #0086)
Kitemark Court,
Davy Avenue,
Knowlhill, Milton Keynes,
MK5 8PP, United Kingdom

YEAR OF CE MARKING: 2015

EC CERTIFICATE NUMBER CE 96026

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

PREPARED BY:

Michelle Cheung
Specialist, Regulatory Affairs07 JULY 2016
Date

MANUFACTURER'S DECLARATION OF CONFORMITY

AUSTRALIAN THERAPEUTIC GOODS (MEDICAL DEVICES) REGULATIONS 2002

This is a declaration of conformity made under clause 1.8 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: 44065 Neurosurgical procedure kit; non-medicated, reusable

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.

Notified Body: BSI Healthcare (ID #0086)
Kitemark Court,
Davy Avenue,
Knowlhill, Milton Keynes,
MK5 8PP, United Kingdom

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

Design examination certificate (if applicable): EC certificate number: CE 96026

Standards Applied: ISO 13485: 2003

Year of CE Marking: 2015



Authorised Signatory:

Michelle Cheung
Specialist, Regulatory Affairs

07 JULY 2016
Date

Attached List to Declaration of Conformity for Precept Spinal System	
Part Number	Part Description
1636026	PRECEPT Tag, Short Tray Base Large
1636027	PRECEPT Tag, Short Tray Base Small
1636028	PRECEPT Tag, Extended Tray Base Large
1636029	PPRECEPT Tag, Extended Tray Base Small
1641596	PRECEPT Tip, Needle Guide Tube
1648728	PRECEPT Tip, Needle Guide Tube
8801002	PRECEPT Driver, K-Wire
8801003	PRECEPT Insulator, First
8801004	PRECEPT Insulator, Tap
8801005	PRECEPT Insulator, Screw
8801006	PRECEPT Insulator, Tap
8801007	PRECEPT Awl, Cannulated
8801008	PRECEPT Guide, Standard
8801009	PRECEPT Guide, Locking Driver
8801010	PRECEPT Slip on Guide
8801011	PRECEPT Tube, Guide
8801012	PRECEPT Adjuster, Guide
8801013	PRECEPT Guide Removal Cap
8801015	PRECEPT Screwdriver, Polyaxial
8801020	PRECEPT Handle, Ratcheting Straight
8801021	PRECEPT Handle, Ratcheting Teardrop
8801022	PRECEPT Screwdriver, Self Retaining
8801023	PRECEPT Rod Measurement Tool
8801024	PRECEPT Tissue Dissector, Curved
8801025	PRECEPT Tissue Dissector, Straight
8801027	PRECEPT Template, 250mm Rod
8801028	PRECEPT Template, 500mm Rod
8801030	PRECEPT Insertor, Obtuse Variable
8801031	PRECEPT Insertor, Fixed Long
8801034	PRECEPT Rod Holder
8801035	PRECEPT Rod Pusher, Threaded
8801036	PRECEPT Rod Pusher
8801038	PRECEPT Starter, Reduction Lock Screw
8801045	PRECEPT Lock Screw Starter, Multi-Load
8801046	PRECEPT Distractor, Rack Compressor
8801050	PRECEPT Compressor, Final

Attached List to Declaration of Conformity for Precept Spinal System	
Part Number	Part Description
8801052	PRECEPT Compressor Arm, Left Short
8801053	PRECEPT Compressor Arm, Left Long
8801054	PRECEPT Compressor Arm, Right Short
8801055	PRECEPT Compressor Arm, Right Long
8801057	PRECEPT Handle, 90lb Torque Limiting
8801061	PRECEPT Slip-On Guide Removal Tool
8801064	PRECEPT Rocker
8801066	PRECEPT Reducer, Single Level
8801070	PRECEPT Handle, Fascial Splitting
8801074	PRECEPT Bulldozer
8801075	PRECEPT T-Handle, Reduction
8801076	PRECEPT Dilator, Offset
8801077	PRECEPT Slip-On Guide, Short
8801081	PRECEPT Driver, Fixed Insert
8801083	PRECEPT Insert, Wiltse
8801088	PRECEPT Guide, Open Top
8801089	PRECEPT Guide, Open Top 1 Level
8801090	PRECEPT Splitting Tool, Reduction Screw
8801091	PRECEPT Reduction Attachment
8801092	PRECEPT Counter Torque, Reduction Screw
8801093	PRECEPT Stabilizer, Reduction Screw
8801095	PRECEPT Screwdriver, Reduction Screw
8801096	PRECEPT Insulator, Reduction Screw
8801097	PRECEPT Insulator, Reduction Screw Tap
8801098	PRECEPT Counter Torque, Reduction
8801099	PRECEPT Head Insert
8801107	PRECEPT Caddy, Open Lock Screw
8801108	PRECEPT Lid, Open Lock Screw
8801137	PRECEPT Insert, Bottom Level
8801138	PRECEPT Insert, Top Level
8801140	PRECEPT Caddy Lid, Tulip
8801145	PRECEPT Tap, 4.5 Double Lead Cannulated
8801146	PRECEPT Loading Block, Polyaxial
8801147	PRECEPT Loading Block, Wiltse Insert
8801151	PRECEPT Base, Extra Guide Tray
8801152	PRECEPT Nuvasive Small Lid
8801155	PRECEPT Tap, 5.5 Double Lead Cannulated
8801165	PRECEPT Tap, 6.5 Double Lead Cannulated

Attached List to Declaration of Conformity for Precept Spinal System

Part Number	Part Description
8801175	PRECEPT Tap, 7.5 Double Lead Cannulated
8801202	PRECEPT Tube, K-Wire Long
8801203	PRECEPT Dilator, Primary
8801204	PRECEPT Dilator, Tap
8801205	PRECEPT Dilator, Screw
8801208	PRECEPT Guide, Standard
8801210	PRECEPT Guide, Slip On
8801211	PRECEPT Tap Dilator Combo
8801212	PRECEPT Adjuster, Guide
8801213	PRECEPT Locking Cap, Guide
8801215	PRECEPT Screwdriver, Polyaxial
8801216	PRECEPT Screwdriver, Short
8801217	PRECEPT Cap, Dilator
8801218	PRECEPT Screwdriver, Polyaxial
8801219	PRECEPT Screwdriver, Spring Loaded
8801222	PRECEPT Adjuster, Screw
8801223	PRECEPT Rod Measurement Tool
8801224	PRECEPT Tissue Dissector, Curved
8801229	PRECEPT Inserter, Fixed
8801231	PRECEPT Inserter, Fixed Long
8801232	PRECEPT Inserter, Acute Long
8801235	PRECEPT Rod Pusher, Threaded
8801236	PRECEPT Rod Pusher
8801238	PRECEPT Pile Driver
8801239	PRECEPT Reduction Attachment
8801240	PRECEPT Lock Screw Attachment, Reduction
8801241	PRECEPT LS Attachment Handle 1.5x
8801242	PRECEPT Grip Reducer
8801243	PRECEPT Starter, Lockscrew
8801244	PRECEPT Driver, Lockscrew
8801245	PRECEPT Starter, Lock Screw Multi-Load
8801249	PRECEPT Compressor, Fulcrum
8801250	PRECEPT Compressor, Final Driver
8801256	PRECEPT Reattachment Tool
8801258	PRECEPT Guide, Counter Torque
8801259	PRECEPT Guide, Open Top Counter Torque
8801261	PRECEPT Removal Tool, Slip-On Guide
8801275	PRECEPT Dilator, Facet Tube

Attached List to Declaration of Conformity for Precept Spinal System

Part Number	Part Description
8801277	PRECEPT Facet Tube
8801280	PRECEPT Inserter, Adjustable
8801281	PRECEPT Driver, Inserter
8801282	PRECEPT Inserter, In-Line
8801286	PRECEPT Multi Tool
8801290	PRECEPT Reduction Splitting Tool
8801291	PRECEPT Reduction Attachment
8801292	PRECEPT Counter Torque, Reduction Screw
8801293	PRECEPT Breakoff Tool, Reduction Screw 1
8801294	PRECEPT Breakoff Tool, Reduction Screw 2
8801295	PRECEPT Screwdriver, Reduction Screw
8801296	PRECEPT Dilator, Reduction Screw
8801297	PRECEPT Dilator, Reduction Tap
8801298	PRECEPT Counter Torque, Open
8801299	PRECEPT Reduction Spreader
8801301	PRECEPT Base, Implant Tray
8801302	PRECEPT Insert, Rod
8801303	PRECEPT Insert, Polyaxial Screw
8801304	PRECEPT Caddy, Polyaxial Screw
8801305	PRECEPT Base, Instrument 1
8801306	PRECEPT Insert, Rod Insertion Ins 1
8801307	PRECEPT Insert, Screw Insertion Ins 1
8801308	PRECEPT Insert, Pedicle Prep Ins 1
8801309	PRECEPT Base, Instrument 2
8801310	PRECEPT Insert, Compression Rod Ins 2
8801311	PRECEPT Insert, Final Tightening Ins 2
8801312	PRECEPT Insert, Red and Lock Screw Ins
8801313	PRECEPT Base, Long Construct
8801314	PRECEPT Insert, Long Construct Ins
8801315	PRECEPT Insert, Long Construct Rod
8801316	PRECEPT Insert, Long Construct Screw
8801318	PRECEPT Base, Open Instrument
8801319	PRECEPT, Open Inst Compr Distr Level
8801320	PRECEPT Insert, Open Instrument
8801321	PRECEPT Base, Reduction
8801322	PRECEPT Insert, Reduction Instrument
8801324	PRECEPT Insert, Reduction Screws
8801329	PRECEPT Demo Caddy

Attached List to Declaration of Conformity for Precept Spinal System	
Part Number	Part Description
8801330	PRECEPT Demo Caddy Lid
8801331	PRECEPT, Open Ins Tray, Extra Level
8801332	PRECEPT Base, Reduction Instrument Tray
8801335	PRECEPT Polyaxial Screw Caddy, 5.5mm
8801336	PRECEPT Polyaxial Screw Caddy, 6.5mm
8801337	PRECEPT Polyaxial Screw Caddy, 7.5mm
8801338	PRECEPT Polyaxial Screw Caddy, 8.5mm
8801339	PRECEPT Polyaxial Screw Caddy, 4.5mm
8801341	PRECEPT Base, Open Top Guide Tray
8801343	PRECEPT Loading Block
8801344	PRECEPT Loading Block, Lid
8801345	PRECEPT Tap, 4.5mm Double Lead Cann
8801346	PRECEPT Loading Block, Leg
8801348	PRECEPT Screwdriver, Reduction Extended
8801349	PRECEPT Adapter, Offset NV Clip
8801350	PRECEPT Tap, 5.0mm Double Lead Cann
8801354	PRECEPT Shankdriver, Mod Extended
8801355	PRECEPT Tap, 5.5mm Double Lead Cann
8801360	PRECEPT Tap, 6.0mm Double Lead Cann
8801361	PRECEPT Tray, Semi-Open
8801365	PRECEPT Tap, 6.5mm Double Lead Cann
8801370	PRECEPT Tap, 7.0mm Double Lead Cann
8801375	PRECEPT Tap, 7.5mm Double Lead Cann
8801385	PRECEPT Tap, 8.5mm Double Lead Cann
8801390	PRECEPT Tap, 9.0mm Double Lead Cann
8801395	PRECEPT Tap, 9.5mm Double Lead Cann
8801405	PRECEPT Guide Holder
8801409	PRECEPT Base, Short Tray
8801410	PRECEPT Pusher, Small
8801411	PRECEPT Pusher, Large
8801413	PRECEPT Adapter, Offset NV Clip with Pin
8801445	PRECEPT Tap, 4.5mm Dbl Lead Cann Short
8801455	PRECEPT Tap, 5.5mm Dbl Lead Cann Short
8801465	PRECEPT Tap, 6.5mm Dbl Lead Cann Short
8801475	PRECEPT Tap, 7.5mm Dbl Lead Cann Short
8801485	PRECEPT Tap, 8.5mm Dbl Lead Cann Short
8801509	PRECEPT Base, Extended Tray
8801515	PRECEPT Base, Fixed Screws Tray

Attached List to Declaration of Conformity for Precept Spinal System	
Part Number	Part Description
8801516	PRECEPT Caddy, Fixed Screws
8801517	PRECEPT Pin Mat, Fixed Screws Tray
8801545	PRECEPT Tap, 4.5mm Dbl Lead Cann Long
8801555	PRECEPT Tap, 5.5mm Dbl Lead Cann Long
8801565	PRECEPT Tap, 6.5mm Dbl Lead Cann Long
8801575	PRECEPT Tap, 7.5mm Dbl Lead Cann Long
8801585	PRECEPT Tap, 8.5mm Dbl Lead Cann Long
8802001	PRECEPT Shank Driver
8802003	PRECEPT Rod Measurement Tool
8803100	PRECEPT Tap, 10.0mm Double Lead Cann
8803105	PRECEPT Tap, 10.5mm Double Lead Cann
8803300	PRECEPT Reduction Instrument Case
8803301	PRECEPT Reduction Tray 1, Ins Case
8803302	PRECEPT Reduction Tray 2, Ins Case
8803303	PRECEPT Reduction Tray 3, Ins Case
8803304	PRECEPT Reduction Base, Ins Case
8803305	PRECEPT Reduction Implant Case
8803306	PRECEPT Reduction Tray 1, Imp Case
8803307	PRECEPT Reduction Tray 2, Imp Case
8803308	PRECEPT Reduction Base, Imp Case
8805100	PRECEPT Tap, 10.0mm Dbl Lead Cann Long
8805105	PRECEPT Tap, 10.5mm Dbl Lead Cann Long
8890008	PRECEPT Base, Guide Bulldozer Tray
8890009	PRECEPT Base, Guide Piledriver Tray
8890014	PRECEPT Tag, Sm Guide Piledriver Tray
8890015	PRECEPT Tag, Lg Guide Piledriver Tray
8890016	PRECEPT Tag, Sm Guide Bulldozer Tray
8890017	PRECEPT Tag, Lg Guide Bulldozer Tray
9501002	PRECEPT Insert, First Layer Demo
9501003	PRECEPT Insert, Second Layer Demo
9501004	PRECEPT Insert, Third Layer Demo
9501006	PRECEPT Lid, with Convuluted Pad Demo
9501007	PRECEPT SKB Case, Demo
9501008	PRECEPT Acrylic Sawbones Model
8801410994	PRECEPT Pusher, Cement Large
8801411994	PRECEPT Pusher, Cement Small
8801416994	PRECEPT Guide, Needle
8801418994	PRECEPT Base, Fenestrate Instrument Tray

Attached List to Declaration of Conformity for Precept Spinal System

Part Number	Part Description
8801419994	PRECEPT Pin Mat, Fen Instrument Tray
8801420994	PRECEPT Base, Fenestrated Screw Tray
8801421994	PRECEPT Caddy, Fenestrated Screw Tray
8801422994	PRECEPT Pin Mat, Fenestrated Screw Tray
D1660016	PRECEPT Screwdriver, Fixed Long
D8801046	PRECEPT Compressor, Rack Dismantlable
D8801074	PRECEPT Bulldozer Dismantlable
D8801208	PRECEPT Guide, Standard Dismantlable
D8801214	PRECEPT Guide, Dismantlable
D8801215	PRECEPT Screwdriver, Poly Dismantlable
D8801229	PRECEPT Insertter, Fixed Dismantlable
D8801238	PRECEPT Pile Driver, Dismantlable
D8801242	PRECEPT Grip Reducer, Dismantlable
D8801249	PRECEPT Compressor, Fulcrum Dismantlable
D8801261	PRECEPT Removal Tool, Slip-On Guide Dism
D8801262	PRECEPT Wrench Tool, Adj Dismantlable
D8801280	PRECEPT Insertter, Adj Dismantlable
D8801289	PRECEPT Screwdriver, Fixed
D8801295	PRECEPT Screwdriver, Red Dismantlable
D8801306	PRECEPT Ins 1 Tray, Rod Insertion
D8801307	PRECEPT Ins 1 Tray, Screw Insertion
D8801311	PRECEPT Ins 2 Tray, Final Tightening
D8801314	Precept Instrument Level, Long Construct
D8801322	Precept Instrument Level, Reduction Tray
8802004	PRECEPT MOD Head Insertter
8890001	PRECEPT Mod Caddy, Tulip
8890002	PRECEPT Mod Lid, Tulip Caddy
8890003	PRECEPT Mod Base, Tray
8890004	PRECEPT Mod Middle, Tray
8890005	PRECEPT Mod Bottom, Tray
8890006	PRECEPT Mod Top, Tray
8890007	PRECEPT Mod Caddy, Shank
8890012	PRECEPT Mod Tag, Large
8890013	PRECEPT Mod Tag, Small
8890022	PRECEPT MOD Dilator, Primary
D8802005	Precept MOD Head Instr Disassembly Tool
D8890004	Precept MOD Middle, Tray Dismantlable
D8890006	Precept MOD Top, Tray Dismantlable
8801260	PRECEPT Reduction Counter Torque
88001015	PRECEPT Sleeve, Fenestrated

Attached List to Declaration of Conformity for Precept Spinal System

Part Number	Part Description
3540011	MAS PLIF Depth Gauge
3540015	MAS PLIF Distractor Tip, Lamina Right
3540016	MAS PLIF Distractor Tip, Lamina Left
3540019	MAS PLIF Base, Distractor Tip Caddy
3540020	MAS PLIF Lid, Distractor Tip Caddy
3540021	MAS PLIF Fixation Dura Protector
3540025	MAS PLIF Distractor Rack
7070005	MAS PLIF Fixation Drill, 4.5mm
7070006	MAS PLIF Drill, 5.0mm
7070007	MAS PLIF Fixation Drill, 5.5mm
7070009	MAS PLIF Fixation Drill, 6.5mm
7070011	MAS PLIF Fixation Tap, 4.5mm
7070012	MAS PLIF Fixation Tap, 5.0mm
7070013	MAS PLIF Fixation Tap, 5.5mm
7070015	MAS PLIF Fixation Tap, 6.5mm
7070018	MAS PLIF Fixation Screwdriver, Neck Grab
7070020	MAS PLIF Handle, Ratcheting Str Long
7070021	MAS PLIF Knob Handle, Compact Ratcheting
7070035	MAS PLIF Fixation Reamer, Lateral Tulip
7070036	MAS PLIF Fixation Reamer, Tulip
7070039	MAS PLIF Fixation Guide
7070041	MAS PLIF Fixation Counter Torque, Open
7070042	MAS PLIF Fixation Insulator, Drill/Tap
7070044	MAS PLIF Fixation Insulator, Guide
7070046	MAS PLIF Fixation Insulator, Driver
7070047	MAS PLIF Fixation Insulator, Rod Hemostat
7070048	MAS PLIF Fixation Reducer Knob
7070051	MAS PLIF Fixation Reduction Tower
7070052	MAS PLIF Fixation Screwdriver
7070053	MAS PLIF Fixation Rod Measurement Tool
7070054	MAS PLIF Insert, Polyaxial Header
7070055	MAS PLIF T-Handle, Verification Torque
7070056	MAS PLIF Starter, Lock Screw Expandable
7070057	MAS PLIF Driver, Lock Screw
7070103	MAS PLIF Fixation Btm, Instrument Tray
7070104	MAS PLIF Fixation Mid, Instrument Tray
7070105	MAS PLIF Fixation Top, Instrument Tray
7070107	MAS PLIF Fixation Base, Implant Case
7070108	MAS PLIF Fixation Bottom, Implant Tray
7070109	MAS PLIF Fixation Top, Implant Tray
7070110	MAS PLIF Loading Block, Screw Assembly
7070111	MAS PLIF Tulip Caddy
7070112	MAS PLIF Lid, Tulip Caddy

Attached List to Declaration of Conformity for Precept Spinal System

Part Number	Part Description
7070113	MAS PLIF Shank Caddy
7070114	MAS PLIF Lid, Shank Caddy
7070117	MAS PLIF Lock Screw Caddy
7070118	MAS PLIF Lid, Lock Screw Caddy
7070119	MAS PLIF Placard, Instrument Case Small
7070121	MAS PLIF Placard, Instrument Case Large
7070139	MAS PLIF Guide, Drill
7070141	MAS PLIF Counter Torque, Open
7070142	MAS PLIF Insulator, Drill/Tap
7070144	MAS PLIF Insulator, Drill Guide
7070146	MAS PLIF Insulator, Driver
7070147	MAS PLIF Compressor
7070151	MAS PLIF Reduction Tower, 40mm
7070152	MAS PLIF Screw Loading Block
7070154	MAS PLIF Driver, Lock Screw
7070155	MAS PLIF Starter, Lock Screw
7070156	MAS PLIF Inserter, Head
7070157	MAS PLIF Head Adjuster
7070158	MAS PLIF Starter, Lock Screw Multi-Load
7070203	MAS PLIF Fixation Bottom, Ins Case
7070204	MAS PLIF Fixation Middle, Ins Case
7070205	MAS PLIF Fixation Top, Ins Case
7070207	MAS PLIF Fixation Base, Imp Case
7070208	MAS PLIF Fixation Bottom, Imp. Case
7070209	MAS PLIF Fixation Top, Imp Case
7070211	MAS PLIF Fixation Caddy, Tulip
7070213	MAS PLIF Fixation Caddy, Shank
7070217	MAS PLIF Fixation Caddy, Lock Screw
7070219	MAS PLIF Fixation Placard, Ins. Case Sm
7070221	MAS PLIF Fixation Placard, Ins. Case Lg
7070223	MAS PLIF Top, Fixation Case
7070224	MAS PLIF Middle, Fixation Case
7070225	MAS PLIF Bottom, Fixation Case
7070305	MAS PLIF Fixation Drill, 4.5mm
7070306	MAS PLIF Fixation Drill, 5.0mm
7070307	MAS PLIF Fixation Drill, 5.5mm
7070309	MAS PLIF Fixation Drill, 6.5mm
7070311	MAS PLIF Fixation Tap 4.5mm
7070312	MAS PLIF Fixation Tap, 5.0mm
7070313	MAS PLIF Fixation Tap, 5.5mm
7070315	MAS PLIF Fixation Tap, 6.5mm
7070316	MAS PLIF Tap, 7.0mm
7070317	MAS PLIF Tap, 7.5mm

Attached List to Declaration of Conformity for Precept Spinal System	
Part Number	Part Description
7070318	MAS PLIF Tap, 8.0mm
7070319	MAS PLIF Tap, 8.5mm
7070320	MAS PLIF Tap, 9.0mm
7070321	MAS PLIF Tap, 9.5mm
7070342	MAS PLIF Insulator, Large Diameter Tap
7070344	MAS PLIF Kerrison Persuader
7070350	MAS PLIF Large Diameter Case
7070351	MAS PLIF Tray 1, Large Diameter Case
7070352	MAS PLIF Tray 2, Large Diameter Case
7070353	MAS PLIF Tray 3, Large Diameter Case
7070354	MAS PLIF Base, Large Diameter Case
7070402	MAS PLIF Insulator, Drill/Tap Short
7070405	MAS PLIF Drill, 4.5mm Short
7070406	MAS PLIF Drill, 5.0mm Short
7070407	MAS PLIF Drill, 5.5mm Short
7070408	MAS PLIF Drill, 6.0mm Short
7070409	MAS PLIF Drill, 6.5mm Short
7070411	MAS PLIF Tap, 4.5mm Short
7070412	MAS PLIF Tap, 5.0mm Short
7070413	MAS PLIF Tap, 5.5mm Short
7070414	MAS PLIF Tap, 6.0mm Short
7070415	MAS PLIF Tap, 6.5mm Short
7070420	MAS PLIF Extended Tray
7077045	MAS PLIF Awl Tap Combo, 4.5mm
7077050	MAS PLIF Awl Tap Combo, 5.0mm
7077055	MAS PLIF Awl Tap Combo, 5.5mm
7077060	MAS PLIF Awl Tap Combo, 6.0mm
7077065	MAS PLIF Awl Tap Combo, 6.5mm
7559147	MAS PLIF Fixation Chisel
D7070139	MAS PLIF Guide, Drill Dismantlable
D7070151	MAS PLIF Red Tower, 40mm Dismantlable
D7771166	MAS PLIF Driver, Posted Shank Dism
D1660016	Long Fixed Screwdriver
11010673	Precept Cement Instrument Tray
88001015	Precept Outer Sleeve