

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.

*Issued pursuant to CHXIV, State of
Sept. 15, 1789, 1 Stat. 68-69; 22
USC 2657; 22USC 2651a; 5 USC
301; 28 USC 1733 et. seq.; 8 USC
1443(f); RULE 44 Federal Rules of
Civil Procedure.*

Rex W. Tillerson
Secretary of State

By *[Signature]*
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 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. tại Washington D.C..... 6. ngày 31/5/2017..
at the

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

8. Số 1771 / 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: Gradient PLUS® 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: 2006

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

PREPARED BY: 
Chris Reah
Specialist, Regulatory Affairs

22 OCTOBER 2013
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: 46653 Spinal fixation plate, non-bioabsorbable

Scope of Application: All

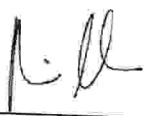
Each kind of medical device to which the system has been applied complies with the applicable provisions of the essential principles, the classification rules, and the full quality assurance procedures, at each stage, from the design of the device until its final inspection before being supplied.

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

Standards Applied: ISO 13485: 2003

Year of CE Marking: 2006

Authorised Signatory:



Chris Reah
Specialist, Regulatory Affairs

22 OCTOBER 2013
Date

ATTACHED LIST TO DECLARATION OF CONFORMITY

FOR

GRADIENT PLUS® SYSTEM INSTRUMENTS

Part Number	Part Description
1010933	LIGHT TIP EXTRUSION
1013399	STERILIZATION CASE - CERVICAL PLATE
1017820	7,7 DEG LEFT END SLOT BASE
1017821	7,7 DEG LEFT END SLOT TUBE
1017822	GUIDE HANDLE (COLOR HANDLE - RED)
1017823	7,7 DEG RIGHT END SLOT BASE
1017824	7,7 DEG RIGHT END SLOT TUBE
1017826	7,0 DEG LEFT END SLOT BASE
1017827	7,0 DEG LEFT END SLOT TUBE
1017829	7,0 DEG RIGHT END SLOT BASE
1017830	7,0 DEG RIGHT END SLOT TUBE
1017832	ROUND HOLE GUIDE BASE
1017833	ROUND HOLE GUIDE TUBE
1017835	FREEHAND GUIDE TUBE
1017837	FREEHAND GUIDE TIP
1017838	7,0 DEG LEFT MIDE SLOT GUIDE BASE
1017839	7,0 DEG LEFT MID SLOT GUIDE TUBE
1017841	7,0 DEG RIGHT MID GUIDE SLOT BASE
1017842	7,0 DEG RIGHT MID GUIDE SLOT TUBE
1017844	7,7 DEG DOUBLE END SLOT BASE
1017845	7,7 DEG RIGHT END SLOT TUBE
1017848	7,0 DEG DOUBLE END SLOT BASE
1017849	7,0 DEG RIGHT END SLOT TUBE
1017852	DOUBLE ROUND HOLE GUIDE BASE
1017853	ROUND HOLE GUIDE TUBE
1017855	7,0 DEG DOUBLE MID SLOT GUIDE BASE
1017856	7,0 DEG RIGHT MID SLOT GUIDE TUBE
1017857	7,0 DEG LEFT MID SLOT GUIDE TUBE
1018149	FREEHAND GUIDE HANDLE
1018165	GUIDE HANDLE (COLOR HANDLE - RED)
1018166	FREEHAND GUIDE TUBE
1018167	7,7 DEG RIGHT END SLOT BASE
1018168	7,0 DEG RIGHT END SLOT BASE
1018169	7,7 DEG LEFT END SLOT BASE
1018170	7,0 DEG LEFT END SLOT BASE
1018171	ROUND HOLE GUIDE TUBE
1018172	ROUND HOLE GUIDE BASE
1018175	FREEHAND GUIDE TIP
1018191	7,0 DEG RIGHT MID GUIDE SLOT BASE
1018192	7,0 DEG RIGHT MID GUIDE SLOT TUBE
1018194	7,0 DEG LEFT MID SLOT GUIDE BASE
1018195	7,0 DEG LEFT MID SLOT GUIDE TUBE
1018196	7,7 DEG RIGHT END SLOT TUBE
1018197	7,0 DEG RIGHT END SLOT TUBE

1018198	7,7 DEG LEFT END SLOT TUBE
1018199	7,0 DEG LEFT END SLOT TUBE
1018237	7,7 DEG DOUBLE END SLOT BASE
1018238	7,0 DEG DOUBLE END SLOT BASE
1018241	7,0 DEG DOUBLE MID SLOT GUIDE BASE
1018242	DOUBLE ROUND HOLE GUIDE BASE
1023850	STERILE DRILL BIT PKG-INNER/OUTER TRAY
1023851	POWER DRILL BIT TRAY INNER
1023852	POWER DRILL BIT TRAY, OUTER
1023853	POWER DRILL BIT SHEATH
7400005	PLATE BENDER
7400010	PLATE HOLDER - HEMOSTAT
7400012	PLATE HOLDER
7400015	TEMPORARY PIN INSERTER
7400016	TEMPORARY PIN
7400021	DRILL TAP SCREW LOCK GUIDE
7400023	FIXED ANGLE DRILL GUIDE
7400024	AO HANDLE
7400025	VARIABLE ANGLE DRILL GUIDE
7400026	DEPTH STOP
7400027	DUAL DRILL GUIDE - FIXED
7400028	FREE-HAND DEPTH STOP
7400029	DEPTH GAUGE
7400030	AWL
7400031	2MM X 10MM DRILL
7400033	2MM ADJUSTABLE DRILL
7400040	4MM X 10MM TAP
7400041	4MM ADJUSTABLE TAP
7400045	4.5MM X 10MM TAP
7400046	4.5MM ADJUSTABLE TAP
7400050	SCREWDRIVER
7400051	SCREW & LOCK DRIVER
7400052	LOCK RECOVERY DRIVER
7400055	LOCK DRIVER
7400070	CERVICAL PL
7400080	IMPLANT STERILIZATION CASE-ASSEMBLY
7440500	SLOT HOLE COVER
7440501	ROUND HOLE COVER
7440800	Gradient Tack, Temporary
7440901	Plate holder
7440902	BONE SCREW DRIVER
7440903	Adjustable drill
7440904	Adjustable tap
7440905	Center punch
7440906	Slot Hole Guide - Left, 7 Deg
7440907	Slot Hole Guide - Right, 7 Deg
7440908	Slot Hole Guide - Left, 0 Deg
7440909	Slot Hole Guide - Right, 0 Deg
7440910	Round Hole Guide

7440911	Freehand Guide
7440912	COVER SCREW DRIVER HANDLE
7440913	Plate bender
7440914	COVER SCREW DRIVER SHAFT
7440915	Slot Hole Guide Mid - Left, 0 Deg
7440916	Slot Hole Guide Mid - Right, 0 Deg
7440917	Power drill bit
7440918	STERILE POWER DRILL BIT
7440920	Case
7440921	Bone Screw Extractor
7440922	Cover Screw Extractor
7440923	Bone Screw Retention Sleeve
7440930	Gradient Plus - Instrument Tray
7440932	Gradient Plus Instrument Level 1 Tray
7440933	Gradient Plus Instrument Tray Base
7441900	Gradient Plus - Implant Tray
7441903	Level 1 Caddy lid Small
7441904	Level 1 Caddy Lid Large
7441905	Level 1 Caddy
7441906	Double Slot Guide - End, 7 Deg
7441907	Gradient Plus Level 1 Tray
7441908	Double Slot Guide - End, 0 Deg
7441909	Level 2 Caddy Lid Small
7441910	Double Round Hole Guide, 0 Deg
7441911	Level 2 Caddy Lid Large
7441912	Level 2 Caddy
7441913	Gradient Plus Implant Tray Base
7441915	Double Slot Guide - Mid, 0 Deg
7442906	FIXED SLOT HOLE GUIDE END - LEFT, 7 DEG
7442907	FIXED SLOT HOLE GUIDE END - RIGHT, 7 DEG
7442908	FIXED SLOT HOLE GUIDE END - LEFT, 0 DEG
7442909	FIXED SLOT HOLE GUIDE END - RIGHT, 0 DEG
7442910	FIXED ROUND GOLE GUIDE - 0 DEG
7442915	FIXED SLOT HOLE GUIDE MID - LEFT, 0 DEG
7442916	FIXED SLOT HOLE GUIDE MID - RIGHT, 0 DEG
7450800	Gradient Tack, Temporary
7450902	Bone screw driver
7450903	Adjustable drill
7450904	Adjustable tap
7450905	Center Punch
7450906	Slot Hole Guide - Left, 7 Deg
7450907	Slot Hole Guide - Right, 7 Deg
7450908	Slot Hole Guide - Left, 0 Deg
7450909	Slot Hole Guide - Right, 0 Deg
7450912	Cover Screw Driver Handle
7450914	Cover Screw Driver Shaft
7450917	POWER DRILL BIT
7450921	Bone Screw Extractor
7451500	SLOT HOLE COVER

7451501	ROUND HOLE COVER
7451906	Double Slot Hole Guide - 7 Deg
7451908	Double Slot Hole Guide - 0 Deg
7451910	Double Round Hole Guide - 0 Deg
7451915	Double Slot Hole Guide - Mid
7452900	LOCKING GUIDE STERILIZATION TRAY
7452901	Gradient Plus DTS Tray Base
7452902	Gradient Plus DTS Tray Lid
7452906	Locking Double Slot Hole Guide - 7 Deg
7452907	Gradient Plus - Dual Locking Guide (Mid)
7452908	Locking Double Slot Hole Guide - 0 Deg
7461500	SLOT HOLE COVER (TORX)
7461501	ROUND HOLE COVER (TORX)
8801334	Generic Lid
CVPLIM	CERVICAL PLATE IMPLANT TRAY
CVPLIN	CERVICAL PLATE INSTRUMENT TRAY
DISC	DISC PREPARATION SET
GDPDTS	GRADIENT PLUS FIXED DTS GUIDE
GDPDTS-SAL	GRADIENT PLUS FIXED DTS GUIDE MODULE
GDPLIM	GRADIENT PLUS IMPLANT TRAY
GDPLIM-SAL	GRADIENT PLUS IMPLANT SET LSC
GDPLIN	GRADIENT PLUS INSTRUMENT TRAY
GDPLIN-SAL	GRADIENT PLUS INSTRUMENT TRAY
GPDEMO	GRADIENT PLUS DEMO KIT
GRADCP	SMARTPLATE® GRADIENT CERV PLATE SYSTEM
GRADFIXDEMO	GRADIENT PLUS FIXED DEMO
GRADIENTPLUS-QTE	GRADIENT PLUS
GRADTRANSDEMO	GRADIENT PLUS TRANSLATIONAL DEMO
LABGDPLIM	GRADIENT PLUS IMPLANT TRAY LAB
LABGDPLIN	GRADIENT PLUS INSTRUMENT SET LAB