

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 third day of August, 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 Kathleen Muldoon
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 danh.....Bộ trưởng ngoại giao.....
acting in the capacity of

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

Hợp chủng quốc Hoa Kỳ.....

được chứng nhận / hợp pháp hóa lãnh sự
Certified

6. tại Washington D.C.....5. ngày 8 / 8 / 2017.....
at the

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

8. Số.....2636 / 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: **Titanium Surgical Mesh (See Attached List)**

CLASSIFICATION: Class I, Rule 8 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: **2010**

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

PREPARED BY: 
Chris Reah
Specialist, Regulatory Affairs

28 NOVEMBER 2016
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: 57806 Vertebral body prosthesis, non-sterile

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: 2010

Authorised Signatory:

Chris Reah
Specialist, Regulatory Affairs

28 NOVEMBER 2016
Date

**ATTACHED LIST TO DECLARATION OF CONFORMITY
FOR VBR SYSTEM**

Part Number	Part Description
1008112	K Medic Narrow Nose Pliers
1008113	K Medic Mesh Pliers
1008750	Mesh Cage Holder, 10.5" Straight
1008751	Mesh Cage Holder, 10.5" Curved
1009202	Autograft Tamp - Straight
1009203	Autograft Tamp - Angled
1010410	Mesh Inserter
1011442	Mesh Plier Large
1011453	Straight Mesh Positioner
1011454	Mesh Positioner Left/Right
1011455	Mesh Positioner Up/Down
1011535	Sterilization Case, Mesh
1599102	Generic Advantis 3 Level Tray, Style A
7100010	Mesh Cutter
7100011	Narrow Nose Pliers
7100012	Mesh Pliers
7100025	Large Mesh Pliers
7100017	Mesh Inserter
7100019	Mesh Holder - Straight
7100020	Mesh Holder - Curved
7100021	Mesh Positioner - Straight
7100022	Mesh Positioner - Left/Right
7100023	Mesh Positioner - Up/Down
7100058	Autograft Tamp - Straight
7100059	Universal Tamp, Autograft Angled
1008111	Mesh Cutter, K Medic
1011455	Mesh Positioner, Up/Down