

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.

Rex W. Tillerson
Secretary of State

By Reo J. Muldrow
Assistant Authentication Officer,
Department of State

*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.*



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 chúng quốc Hoa Kỳ

được chứng nhận / hợp pháp hóa lãnh sự
Certified

5. tại Washington D.C 6. 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: **Monolith Corpectomy System Instruments (See Attached List)**

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

CONFORMITY ASSESSMENT ROUTE: Annex VII

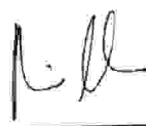
We herewith declare that the abovementioned products meet the provisions of the Council Directive 93/42/EEC for medical devices. All supporting documentation is retained under the premises of the manufacturer.

STANDARDS APPLIED: ISO 13485: 2003

YEAR OF CE MARKING: 2015

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

PREPARED BY:


Chris Reah
Specialist, Regulatory Affairs

26 APRIL 2017
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: 2015

Authorised Signatory:



Chris Reah
Specialist, Regulatory Affairs

26 APRIL 2017
Date

ATTACHED LIST TO DECLARATION OF CONFORMITY FOR MONOLITH SYSTEM INSTRUMENTS

Part Number	Part Number
5771001	Universal Mallet, Cervical
5995105	Monolith Calipers
5995121	Monolith Trial, Core
5995122	Monolith Trial, Endcap 15x13/17x14
5995123	Monolith Trial, Endcap 17x15/19x16
5995124	Monolith Trial, Endcap Ø14/Ø16
5995130	Monolith Core Calculator, Ø12 Cores
5995135	Monolith Core Calculator, Ø14 Cores
5995140	Monolith Loading Block
5995145	Monolith Loading Tool, Graft
5995160	Monolith Positioning Tool, Implant
5995165	Monolith Tamp
5995170	Monolith Removal Tool, Endcap
5995201	Monolith Base, Instrument Tray
5995202	Monolith Top Tray, Instrument Tray
5995203	Monolith Bottom Tray, Instrument Tray
5995204	Monolith Nipple Mat, Instrument Tray
5995207	Monolith Base, Implant Tray Ø12 1-2L
5995208	Monolith Base, Implant Tray Ø14 1-2L
5995209	Monolith Nipple Mat, Implant Tray
5995210	Monolith Caddy, 10-33xØ12 Cores
5995213	Monolith Caddy, 35-49xØ12 Cores
5995214	Monolith Caddy, 10-33xØ14 Cores
5995217	Monolith Caddy, 35-59xØ14 Cores
5995219	Monolith Caddy, Ø12 Core Endcaps
5995220	Monolith Caddy, Ø14 Core Endcaps
5995225	Monolith Base, Implant Tray Ø12 3
5995226	Monolith Base, Implant Tray Ø14 3L
7674101	PCM Slap Hammer
8801300	NuVasive Generic Tray Lid
11010427	Universal Lid, Half Tray
D5995100	Monolith Insertter
5995150	Monolith Tamp, Funnel Graft
5995155	Monolith Funnel
5995156	Monolith Funnel, 14mm
5995157	Monolith Funnel, 12mm/14mm Combination
5995175	Monolith Insertter Stem
5995180	Monolith Thumbwheel, Insertter
5995205	Monolith Base, Implant Tray Ø12 1-2L
5995206	Monolith Base, Implant Tray Ø14 1-2L
9402158	Monolith Master Label
9501443	Monolith Technique Guide
9501444	Monolith Sales Brochure
9501474	Monolith Measurement Wheel, 14mm Core
9501475	Monolith Measurement Wheel, 12mm Core
5995150	Monolith Tamp, Funnel Graft
5995155	Monolith Funnel



MONOLITH™

5995156	Monolith Funnel, 14mm