

**DECLARATION OF CONFORMITY**

**MANUFACTURER:** **NuVasive, Inc.**  
7475 Lusk Blvd.  
San Diego, CA 92121  
United States of America  
+1 858 909 1800

**EUROPEAN REPRESENTATIVE:** **NuVasive Netherlands B.V.**  
Jachthavenweg 109A  
1081 KM Amsterdam  
The Netherlands  
+31 20 72 33 000

**PRODUCT:** **VuePoint OCT/II System Disposable Instruments**  
(see Attached List)

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

**CONFORMITY ASSESSMENT ROUTE:** **Annex II excluding section 4**

**GMDN CODE AND TERM:** 61300 Internal spinal fixation procedure kit, single-use

*Under the sole responsibility of the manufacturer, 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 13485:2016, ISO 16061:2015

**NOTIFIED BODY:** BSI Group The Netherlands B.V. **(NB #2797)**  
Say Building  
John M. Keynesplein 9  
1066 EP Amsterdam  
The Netherlands

**YEAR OF CE MARKING:** 2008

**EC CERTIFICATE NUMBER:** CE 96026

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

**PREPARED BY:**

---

Deepthi Badarinath  
Specialist, Regulatory Affairs

**4<sup>TH</sup> FEB 2021**

**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, Inc.

**BUSINESS ADDRESS:** 7475 Lusk Blvd.  
San Diego, CA 92121  
United States of America  
+1 858 909 1800

**MEDICAL DEVICE(S):** **VuePoint OCT/II System Disposable Instruments** (see Attached List)

**CLASSIFICATION:** **Class IIa** - Classification rule Schedule 2, Part 3.2(2)

**GMDN CODE AND TERM:** 61300 Internal spinal fixation procedure kit, single-use

**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:** EC Certificate – Full Quality Assurance System  
Certificate Number: CE 96026

**STANDARDS APPLIED:** ISO 13485:2016, ISO 16061:2015

**AUTHORISED SIGNATORY:**

\_\_\_\_\_  
Deepthi Badarinath  
Specialist, Regulatory Affairs

**4<sup>TH</sup> FEB 2021**

**ATTACHED LIST TO DECLARATION OF CONFORMITY  
FOR VUEPOINT OCT/II SYSTEM DISPOSABLE INSTRUMENTS**

| <b>PART NUMBER</b> | <b>PART DESCRIPTION</b>                 | <b>GMDN Code</b> |
|--------------------|---|------------------|
| 1886015            | VPII Drill, 2.40mm Equivalent           | 61300            |
| 1886016            | VPII Drill, 2.40mm Exceed               | 61300            |
| 1886017            | VPII Drill, 2.40mm Avalign              | 61300            |
| 7901091            | VuePoint Drill Bit, 2.05mm              | 61300            |
| 7907010            | VuePoint Drill Bit, 2.05mm              | 61300            |
| 7907012            | VuePoint Drill Bit, 2.05mm              | 61300            |
| 7907013            | VuePoint Drill Bit, 2.05mm Short        | 61300            |
| 7907014            | VuePoint Drill Bit, 2.05mm              | 61300            |
| 7907220            | VuePoint Template, 120mm Rod            | 61300            |
| 7907240            | VuePoint Template, 240mm Rod            | 61300            |
| 7907300            | VP Shaft, 3.35mm Occip Drill Bit Str    | 61300            |
| 7907336            | VuePoint Template, 35mm Keel Plate      | 61300            |
| 7907341            | VuePoint Template, 40mm Keel Plate      | 61300            |
| 7907346            | VuePoint Template, 45mm Keel Plate      | 61300            |
| 7917013            | VuePoint Overlay, Drill Bit 2.05m Short | 61300            |
| 8797010            | VuePoint Drill Bit, 2.40mm              | 61300            |
| 8970120            | VuePoint II Template, 120mm Rod         | 61300            |
| 8970240            | VuePoint II Template, 240mm Rod         | 61300            |
| 8977010            | VuePoint II Drill Bit                   | 61300            |
| 8977220            | VuePoint II Template, 120mm Rod         | 61300            |
| 8977240            | VuePoint II Template, 240mm Rod         | 61300            |
| 8977380            | VuePoint II Drill Bit, Angled Occipital | 61300            |
| 8977810            | VuePoint II Drill Bit, XT               | 61300            |
| 8801610P           | NAV.S VuePoint II Drill Bit             | 61300            |
| 8977010P           | VuePoint II Drill Bit                   | 61300            |
| 8970120P           | VuePoint II Template, 120mm Rod         | 61300            |
| 8970240P           | VuePoint II Template, 240mm Rod         | 61300            |