# EC Declaration of Conformity

**Manufacturer:**
Medtronic Navigation, Inc.
826 Coal Creek Circle
Louisville, CO 80027 USA

**European Representative:**
Medtronic B.V.
Earl Bakkenstraat 10
6422 PJ Heerlen
The Netherlands
Tel: 31 45 566 80 00

**Notified Body:**
DEKRA Certification B.V.
Meander 1051, 6825 MJ
Arnhem, The Netherlands
Telephone: +31 88 96 83000
Telefax: +31 88 96 83100

**Name of Device:**
*Class IIa Non Active Non Sterile*
Instruments and Accessories

**Reference/Part Number(s), Description, Conformity Assessment Pathway, Classification, Rule and CE marking date are on the attached sheets.**

*This declaration is issued under the sole responsibility of Medtronic Navigation, Inc. We hereby declare that the products described herein comply with the provisions of the European Medical Devices Directive 93/42/EEC including amendments issued.*

*This declaration is supported by:*

EC Certification under Annex II, Cert No. 3814174CE01 issued by DEKRA Certification B.V., Meander 1051, 6825 MJ, Arnhem, The Netherlands on 15 July 2015. Valid from 15 July 2015 until 8 July 2018.

Quality System Certification to ISO 13485:2012/AC: 2012, Cert No. 3814381issued by DEKRA Certification B.V., Meander 1051, 6825 MJ, Arnhem, The Netherlands on 15 July 2015. Valid from 15 July 2015 until 31 August 2017.

*Applied Standards:*

| Number | Title |
|---|---|
| EN ISO 13485 | Medical Device- Quality Management system- Requirements for regulatory purposes |
| EN ISO 14971 | Medical Devices – Application of risk management to medical devices |
| AAMI TIR No. 12 | Designing, Testing, and Labeling Reusable Medical Devices for Reprocessing in Health Care Facilities: A Guide for Device Manufacturers |
| ANSI/AAMI ST35 | Good Hospital Practice: Safe Handling and Biological Decontamination of Reusable Medical Devices in Health Care Facilities and Nonclinical Settings |
| ISTA 2A | Partial Simulation Performance Test Procedure for Packaged Products 150lb. (68 kg) or Less |
| EN ISO 62366 | Medical devices – Application of usability engineering to medical devices |
| EN 1041 | Information supplied by the manufacturer of medical devices |
| EN ISO 10993-1 | Biological evaluation of medical devices Part 1: Evaluation and testing within a risk management process |
| EN 980 | Symbols for use in the labeling of medical devices |

M Blasco
(Signature)

12-Aug-2015
(Date)

Michael Blasco
Senior Manager, Regulatory Affairs
Louisville, CO USA

| REF | DESCRIPTION | CE Class | Rule | Pathway | CE Date | GMDN |
|---|---|---|---|---|---|---|
| 9731780 | INST 9731780 OPEN SPINE CLAMP, TI | IIa | 7 | Annex II.3 | 7/15/2015 | 45199 |
| 9732520 | BASE 9732520 QUICK RELEASE | IIa | 7 | Annex II.3 | 7/15/2015 | 45199 |
| 9732563 | CANNULA, 9732563, 100MM | IIa | 7 | Annex II.3 | 7/15/2015 | 34004 |
| 9732772 | CANNULA, 9732772, 150MM | IIa | 7 | Annex II.3 | 7/15/2015 | 34004 |
| 9733037 | CLAMP, 9733037, AXIEM SPINE REFERENCE | IIa | 7 | Annex II.3 | 7/15/2015 | 45199 |
| 9733148 | CLAMP, 9733148, THORACIC, RADIOLUCENT | IIa | 7 | Annex II.3 | 7/15/2015 | 45199 |
| 9734715 | Clamp 9734715 Spinous Process Tall | IIa | 7 | Annex II.3 | 7/15/2015 | 45199 |
| 9734715K | Clamp 9734715K Spinous Process Tall Kit | IIa | 7 | Annex II.3 | 7/15/2015 | 45199 |
| 9734716 | Clamp 9734716 Spinous Process Short | IIa | 7 | Annex II.3 | 7/15/2015 | 45199 |
| 9734716K | Clamp 9734716K Spinous Process Short Kit | IIa | 7 | Annex II.3 | 7/15/2015 | 45199 |
| 9734723 | Clamp 9734723 Double Process Tall | IIa | 7 | Annex II.3 | 7/15/2015 | 45199 |
| 9734723K | Clamp 9734723K Double Process Tall Kit | IIa | 7 | Annex II.3 | 7/15/2015 | 45199 |
| 9734724 | Clamp 9734724 Double Process Short | IIa | 7 | Annex II.3 | 7/15/2015 | 45199 |
| 9734724K | Clamp 9734724K Double Process Short Kit | IIa | 7 | Annex II.3 | 7/15/2015 | 45199 |
| 9734741 | Reference 9734741 Rod 4.75 | IIa | 7 | Annex II.3 | 7/15/2015 | 45199 |
| 9734741K | Reference 9734741K Rod 4.75 Kit | IIa | 7 | Annex II.3 | 7/15/2015 | 45199 |
| 9734742 | Reference 9734742 Rod 5.5/6.0 | IIa | 7 | Annex II.3 | 7/15/2015 | 45199 |
| 9734742K | Reference 9734742K Rod 5.5/6.0 Kit | IIa | 7 | Annex II.3 | 7/15/2015 | 45199 |
| 9734743 | Reference 9734743 Rod 6.35 | IIa | 7 | Annex II.3 | 7/15/2015 | 45199 |
| 9734743K | Reference 9734743K Rod 6.35 Kit | IIa | 7 | Annex II.3 | 7/15/2015 | 45199 |
| 9735129 | INST KIT 9735129 SPINE CLAMP | IIa | 7 | Annex II.3 | 7/15/2015 | 45199 |
| 9735136 | INST KIT 9735136 CANNULA 100 | IIa | 7 | Annex II.3 | 7/15/2015 | 34004 |
| 9735137 | INST KIT 9735137 CANNULA 150 | IIa | 7 | Annex II.3 | 7/15/2015 | 34004 |
| 9735164 | INST KIT 9735164 LIGHT REF CLAMP | IIa | 7 | Annex II.3 | 7/15/2015 | 45199 |
| 9735132 | INST KIT 9735132 CLAMP THORACIC | IIa | 7 | Annex II.3 | 7/15/2015 | 45199 |
| 9735144 | INST KIT 9735144 CLAMP PERC LONG | IIa | 7 | Annex II.3 | 7/15/2015 | 45199 |
| 9735145 | INST KIT 9735145 CLMP PERC SHRT | IIa | 7 | Annex II.3 | 7/15/2015 | 45199 |
| 9735251 | Clamp 9735251 Rod Tall | IIa | 7 | Annex II.3 | 7/15/2015 | 45199 |
| 9735251K | Clamp 9735251K Rod Tall Kit | IIa | 7 | Annex II.3 | 7/15/2015 | 45199 |
| 9735252 | Clamp 9735252 Rod Short | IIa | 7 | Annex II.3 | 7/15/2015 | 45199 |
| 9735252K | Clamp 9735252K Rod Short Kit | IIa | 7 | Annex II.3 | 7/15/2015 | 45199 |
| 963-791 | INST 963-791 PERCUTANEOUS CLAMP, LONG | IIa | 7 | Annex II.3 | 7/15/2015 | 45199 |
| 963-792 | INST 963-792 PERCUTANEUS CLAMP, SHORT | IIa | 7 | Annex II.3 | 7/15/2015 | 45199 |