

## EC Declaration of Conformity

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**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 Sterile: Trajectory Guide Kits,  
Pak Needles, Pins, Drill Bits, Adhesive Pad and  
Spheres

**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, excluding Section 4, Cert No. 3814174CE01  
issued by DEKRA Certification B.V., Meander 1051, 6825 MJ, Arnhem, The  
Netherlands on 28 June 2018. Valid from 15 July 2015 until 08 July 2023.

EN ISO 13485:2016, Cert No. 3814381 issued by DEKRA Certification B.V.,  
Meander 1051, 6825 MJ, Arnhem, The Netherlands on 10 February 2020. Valid  
from 15 July 2015 until 10 August 2020.

*Applied Standards:*

<b>Standard</b>	<b>Title</b>
EN ISO 13485:2016	Medical device – Quality management systems – Requirements for regulatory purposes
EN ISO 14971:2012	Medical devices – Application of risk management to medical devices
EN ISO 11607-1:2009	Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems
EN ISO 11607-2:2006	Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes
ASTM D4169:2016	Standard Practice for Performance Testing of Shipping Containers and Systems
ISTA 2A:2012	Partial Simulation Performance Test Procedure for Packaged Products 150lb. (68 kg) or Less
ASTM F1980:2016	Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices
EN 62366:2008	Medical devices – Application of usability engineering to medical devices
EN 1041:2008	Information supplied by the manufacturer of medical devices
EN ISO 10993-1:2009/AC:2010	Biological Evaluation of Medical Devices – Part 1: Evaluation and testing within a risk management process
EN ISO 10993-7:2008/AC:2009	Biological Evaluation of Medical Devices – Part 7: Ethylene oxide sterilization residuals
EN ISO 11135-1:2007	Sterilization of health care products – Ethylene oxide - Part 1: Requirements for development validation and routine control of a sterilization process for medical devices
EN ISO 15223-1:2016	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements



(Signature)

04-Mar-2020

(Date)

Rishi Sinha  
 Senior Manager, Regulatory Affairs  
 Louisville, CO 80027  
 USA

REF	DESCRIPTION	CE Class	Rule	Pathway	CE Date	GMDN
9732500	ADHESIVE PAD 9732500 HEAD TRACKER 25 PK	IIa	1	Annex II.3	7/15/2015	45199
9732537	PIN PK 9732537 STERILE 125MM 2PK	IIa	7	Annex II.3	7/15/2015	45199
9732538	PIN 9732538 75MM STERILE 2PK	IIa	7	Annex II.3	7/15/2015	45199
9733065	TRAJ GUIDE KIT, 9733065, BIOPSY, EXT	IIa	7	Annex II.3	7/15/2015	38563
9733066	TRAJ GUIDE KIT, 9733066, BIOPSY, INT	IIa	7	Annex II.3	7/15/2015	38563
9733067	TRAJ GUIDE KIT, 9733067, CATHETER, ELEV	IIa	7	Annex II.3	7/15/2015	32568
9733088	PIN 9733088 125MM SINGLE PACKAGED	IIa	7	Annex II.3	7/15/2015	45200
9733089	PIN 9733089, 75MM, SINGLE PACKAGED	IIa	7	Annex II.3	7/15/2015	45200
9733229	ADHESIVE PAD 9733229 H- TRACKER, SINGLE	IIa	1	Annex II.3	7/15/2015	45199
9733235	PIN, 9733235, 100MM, STERILE, PERC REF	IIa	7	Annex II.3	7/15/2015	62546
9733236	PIN, 9733236, 150MM, STERILE, PERC REF	IIa	7	Annex II.3	7/15/2015	62546
9733324	SCREW, 9733324, ACC., 6 PK – 1.6 X 8.0 MM	IIa	7	Annex II.3	7/15/2015	45199
9733497	PAK 9733497NAV NIM- SPINE PEDICLE ACC KT	IIa	6	Annex II.3	7/15/2015	45170
9733498	PAK 9733498 NAVIGATED PEDICLE ACCESS KIT	IIa	6	Annex II.3	7/15/2015	45199
9733515	BIT 9733515 2.4mm DRILL STERILE	IIa	6	Annex II.3	7/15/2015	45553
9733516	BIT 9733516 2.9mm DRILL STERILE	IIa	6	Annex II.3	7/15/2015	45553
9733517	BIT 9733517 3.0mm DRILL STERILE	IIa	6	Annex II.3	7/15/2015	45553
9733518	BIT 9733518 3.5mm DRILL STERILE	IIa	6	Annex II.3	7/15/2015	45553
9733519	BIT 9733519 3.0mm CANNULATED STERILE	IIa	6	Annex II.3	7/15/2015	45553