

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

Name of Device: *Class I Active Non Sterile Devices:
Navigational Platforms, Platform Accessories and Interface Devices*

**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:

Quality System Certification to ISO 13485:2014/AC: 2014, Cert No.
3814381 issued 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
EN 60601-1	General requirements for basic safety and essential performance
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
EN 62304	Medical device software – Software lifecycle processes



(Signature)

18-Nov-2015

(Date)

Michael Blasco
Senior Manager, Regulatory Affairs
Louisville, CO USA

REF	DESCRIPTION	CE Class	Rule	Pathway	CE Date	GMDN
9660651	SYSTEM, 9660651, AXIEM PORTABLE	I	12	Annex VII	7/15/2015	45199
9730259	INST 9730259 TRACKER, ACTIVE WIRELESS	I	12	Annex VII	7/15/2015	45199
9731203	FIELD GENERATOR 9731203 EM MOBILE	I	12	Annex VII	7/15/2015	45199
9731256	INST 9731256 UNIV PADDLE 1.27MM	I	12	Annex VII	7/15/2015	45200
9731457	ZEISS PENTERO HARDWARE – PLUS	I	12	Annex VII	7/15/2015	45199
9731463	HARDWARE 9731463 MOELLER 20-1000 PTR	I	12	Annex VII	7/15/2015	45199
9731464	BRACKET ADAPTER 9731464 MOLLER 20-1000	I	12	Annex VII	7/15/2015	45199
9731465	ZEISS PENTERO HARDWARE – SCOPE	I	12	Annex VII	7/15/2015	45199
9731460	LED BRACKET 9731460 ZEISS PENTERO	I	12	Annex VII	7/15/2015	45199
9731634	LED BRACKET, 9731634, ZEISS VARIO	I	12	Annex VII	7/15/2015	45199
9731736	FOOTSWITCH 9731736 WITH CABLE, HC	I	1	Annex VII	7/15/2015	45199
9731958	INSTALL CD, 9731958, SPINE TOOLS, PLUS	I	12	Annex VII	7/15/2015	45199
9732178	KIT, 9732178, STEALTHLINK	I	12	Annex VII	7/15/2015	45199
9732180	CD, LIBRARY – STEALTHLINK	I	12	Annex VII	7/15/2015	45199
9732222	FLUORO TRACKER, 9732222, WIRELESS 9"	I	12	Annex VII	7/15/2015	45199
9732247	FLUORO TRACKER, 9732247, WIRELESS 12"	I	12	Annex VII	7/15/2015	45199
9732745	AXIEM KIT, 9732745, PORTABLE, 220V	I	12	Annex VII	7/15/2015	45199
9732750	AXIEM KIT, 9732750, PORTABLE PRE-BUILD	I	12	Annex VII	7/15/2015	45195
9732776	RK KIT, 9732776, WRLESS, 9 IN, 96-9800	I	1	Annex VII	7/15/2015	45199
9732777	TRK KIT, 9732777, WRLESS, 12IN, 96-9800	I	12	Annex VII	7/15/2015	45199
9732778	TRK KIT, 9732778, WRLESS, 9 IN, PHILIPS	I	12	Annex VII	7/15/2015	45199
9732779	TRK KIT, 9732779, WRLESS, 12IN, PHILIPS	I	12	Annex VII	7/15/2015	45199
9732780	TRK KIT, 9732780, WRLESS, 9 IN, SIEMENS	I	12	Annex VII	7/15/2015	45199
9732811	SOFTWARE, MICROCAL, PLUS	I	12	Annex VII	7/15/2015	45199
9732829	TRK KIT, 9732829, WRLESS, 9 IN NAVLNK	I	12	Annex VII	7/15/2015	45199
9733048	HW INTERFACE, 9733048, ISOC3D/ORBIC	I	12	Annex VII	7/15/2015	45199
9733153	CD, 9733153, LIBRARY STEALTHLINK WINDOWS	I	12	Annex VII	7/15/2015	45199
9733155	STEALTHLINK KIT, 9733155, WINDOWS	I	12	Annex VII	7/15/2015	45199
9733301	Tracker, 9733301, Wireless O-arm, Right	I	12	Annex VII	7/15/2015	37649
9733302	Tracker, 9733302, Wireless O-arm, Left	I	12	Annex VII	7/15/2015	37649
9733303	TRACKER KIT, 9733303, O-ARM WIRELESS	I	12	Annex VII	7/15/2015	37649
9733320	SYSTEM 9733320 AxiEM INTEGRATED 4 PORT	I	12	Annex VII	7/15/2015	45199
9733459	ARM 9733459 EMITTER HOLDER	I	12	Annex VII	7/15/2015	45199
9733469	CLAMP, 9733469, EMITTER HOLDER	I	12	Annex VII	7/15/2015	45199
9733470	CART, FUSION, STANDARD	I	12	Annex VII	7/15/2015	45199
9733472	CART SUBASSEMBLY 9733472 FUSION	I	12	Annex VII	7/15/2015	45199
9735323	INSTALL MEDIA 9735323 ENT TOOLS	I	12	Annex VII	7/15/2015	45199
9733808	SOFTWARE 9733808 DICOM Q/R	I	12	Annex VII	7/15/2015	45199
9733857	CART 9733857 S7 SURGEON LCD ASSEMBLED	I	12	Annex VII	7/15/2015	45199
9733858	CART 9733858 S7 ASSEMBLED STAFF 220V	I	12	Annex VII	7/15/2015	45199
9733880	PROBE 9733880 LINEAR SHARP HC	I	12	Annex VII	7/15/2015	45199
9733881	FRAME 9733881 CRANIAL ACTIVE HC	I	12	Annex VII	7/15/2015	45199
9733883	TRACKER 9733883 LEICA MICROSCOPE	I	12	Annex VII	7/15/2015	32568
9733884	FIGHTER 9733884 SURETRAK2 ACTIVE HC	I	12	Annex VII	7/15/2015	45199
9733885	FIGHTER 9733885 ACTIVE HC	I	12	Annex VII	7/15/2015	45199
9733886	FRAME 9733886 SMALL ACTIVE HC	I	12	Annex VII	7/15/2015	45199
9733887	FRAME 9733887 ORTHO HC	I	12	Annex VII	7/15/2015	45200
9733933	SFTWR KIT 9733933 DICOM SOFTWARE Q/R	I	12	Annex VII	7/15/2015	45199

REF	DESCRIPTION	CE Class	Rule	Pathway	CE Date	GMDN
9734048	PLNG STATION 9734048 STEALTHSTATION S7	I	12	Annex VII	7/15/2015	45195
9734061	EQUIPMENT RACK 9734061 i7 220V	I	12	Annex VII	7/15/2015	45199
9734063	NAVIGATION INTERFACE 9734063 i7 220V	I	12	Annex VII	7/15/2015	45199
9734232	Cart 9734232 S7 Staff Short 220V Intl	I	12	Annex VII	7/15/2015	45199
9734314	RACK ASSEMBLY 9734314 i7 GENERIC	I	12	Annex VII	7/15/2015	45199
9734350	ADAPTER 9734350 OH4 MOUNT KIT	I	12	Annex VII	7/15/2015	32568
9734354	ADAPTER 9734354 OH5 MOUNT KIT	I	12	Annex VII	7/15/2015	32568
9734685	Cart 9734685 S7 Surg Touch LCD Assembled	I	12	Annex VII	7/15/2015	45199
9734862	CD 9734862 STEALTHLINK LIBRARY	I	12	Annex VII	7/15/2015	45199
9734895	CART 9734895 S7 STAFF AXIEM ONLY 220V	I	12	Annex VII	7/15/2015	45199
9735345	Software 9735345 Install Media Tools DB	I	12	Annex VII	7/15/2015	45199
9735379	INSTALL MEDIA 9735379 CRANIAL TOOLS	I	12	Annex VII	7/15/2015	45199
960-152	SFTWR 960-152 MEDIA IO	I	12	Annex VII	7/15/2015	45199
960-774	ACC 960-774 ALOKA MP2458 VERIF DEV	I	6	Annex VII	7/15/2015	40761
961-413	ACC 961-413 LED BRACKETS	I	12	Annex VII	7/15/2015	45199
961-477	ACC 961-477 NC4 LED BRACKET	I	12	Annex VII	7/15/2015	45199
960-774	ACC 960-774 ALOKA MP2458 VERIF DEV.	I	6	Annex VII	7/15/2015	40761
9730259R	TRACKER 9730259R STEALTH WIRELESS RWK	I	12	Annex VII	7/15/2015	45199
9731203R	FIELD GENERATOR, 9731203R EM MOBILE	I	12	Annex VII	7/15/2015	45195
9732222R	TRACKER, 9732222R, WRISS FLUORO REWORK	I	12	Annex VII	7/15/2015	45199
9733048R	HW INTERFACE, 9733048, ISOC3D/ORBIC	I	12	Annex VII	7/15/2015	45199
9733857R	CART 9733857R S7 SURGEON LCD REWORK	I	12	Annex VII	7/15/2015	45199
9733858R	CART 9733858R S7 STAFF REWORK 220V	I	12	Annex VII	7/15/2015	45199
9734685R	Reworked Surgeon Monitor Cart with Touch Screen	I	12	Annex VII	7/15/2015	45199
9734895R	CART, S7 AXIEM ONLY, 220V, REWORK	I	12	Annex VII	7/15/2015	45199
9735550	STAND 973550 FUSION COMPACT	I	12	Annex VII	11/18/2015	45199