Medtronic

DD008 DoC, Rev. 6

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:	CNS Planar Blunt and CNS Microscope Probes

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 (4), 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 08 July 2018.

EC Design Examination Certificate under Annex II, Section 4, Cert No. 3814174DE05 issued by DEKRA Certification B.V., Meander 1051, 6825 MJ, Arnhem, The Netherlands on 15 July 2015. Valid from 30 April 2016 until 02 May 2019.

Quality System Certification to ISO 13485:2012/AC: 2012 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:

Standard	Title
EN ISO 13485	Medical devices – Quality management systems – Requirements for regulatory purposes
EN ISO 14971	Medical devices – Application of risk management to medical devices
EN ISO 10993-1	Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process
EN ISO 10993-5	Biological evaluation of medical devices- Part 5 Test for in vitro cytotoxicity
EN 13727	Chemical disinfectants and antiseptics –Qualitative suspension test for the evaluation of bactericidal activity of chemical disinfectants for instruments used in the medical area-Test Method and requirements (Phase 2, Step 1)
EN ISO 15883-1	Washer-disinfectors-Part 1:General requirements, terms and definitions and tests (ISO 15883-1:2006)
EN ISO 15883-2	Washer-disinfectors Part 2: Requirements and tests for washer-disinfectors employing thermal disinfection for surgical instruments
EN 980	Symbols for use in the labeling of medical devices
EN 1041	Information supplied by the manufacturer of medical devices
EN ISO 17665-1	Sterilization of health care products -- Moist heat -- Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices
EN ISO 17664	Sterilization of medical devices -- Information to be provided by the manufacturer for the processing of resterilizable medical devices
EN ISO 11607-1	Packaging for terminally sterilized medical devices

02-May-2016

(Signature) (Date)

Michael Blasco
Sr. Manager Regulatory Affairs
Louisville, CO USA

REF	DESCRIPTION	CE Class	Rule	Pathway	CE Date	GMDN
9734881	CNS Planar Blunt Probe	III	6	Annex II.3 & II.4	2015-07-15	45169
9734889	CNS Microscope Probe	III	6	Annex II.3 & II.4	2015-07-15	45169