EC CERTIFICATE

Number: 3814174CE01

Full Quality Assurance System

Directive 93/42/EEC on Medical devices, Annex II excluding (4)
(Devices in Class IIa, IIb or III)

Manufacturer:

Medtronic Navigation, Inc.

826 Coal Creek Circle
Louisville, CO 80027
United States Of America

For the product category(ies)

Image Guided Surgery Systems and Accessories

DEKRA grants the right to use the EC Notified Body Identification Number illustrated below to accompany the CE Marking of Conformity on the products concerned conforming to the required Technical Documentation and meeting the provisions of the EC-Directive which apply to them:

0344

Documents that form the basis of this certificate:

Certification Notice 3814174CN, initially dated 15 July 2015
Addendum, initially dated 15 July 2015

DEKRA hereby declares that the above mentioned manufacturer fulfils the relevant provisions of 'Besluit Medische Hulpmiddelen', the Dutch transposition of the Council Directive 93/42/EEC of June 14, 1993 concerning Medical devices, including all subsequent amendments. The manufacturer has implemented a quality assurance system for design, manufacture and final inspection for the above mentioned product category in accordance to the provisions of Annex II of Council Directive 93/42/EEC of June 14, 1993 and is subject to periodical surveillance. For placing on the market of Class III devices an additional EC design examination certificate according to Annex II (4) is mandatory. The necessary information related to the quality management system of the manufacturer, including facilities and the reference to the relevant documentation, of the products concerned and the assessments performed, are stated in the Certification Notice which forms an integrative part of this certificate.

This certificate is valid until: 8 July 2023
Issued for the first time: 15 July 2015
Revised: 29 October 2015
Reissued: 28 June 2018

DEKRA Certification B.V.

drs. G.J. Zoetbrood
Managing Director

ing. A.A.M. Laan
Certification Manager

DEKRA Certification B.V. is Notified Body with ID no 0344

DEKRA Certification B.V. Meander 1051, 6825 MJ Arnhem P.O. Box 5185, 6802 ED Arnhem, The Netherlands
T +31 88 96 83000 F +31 88 96 83100 www.dekra-certification.com Company registration 09085396

ADDENDUM

Belonging to certificate: 3814174CE01

CE MARKING OF CONFORMITY
MEDICAL DEVICES

Image Guided Surgery Systems and Accessories

Issued to:

Medtronic Navigation, Inc.
826 Coal Creek Circle
Louisville, CO 80027
United States Of America

This certificate covers the following product(s):

Instrument/Patient Tracker, Blades, Touch-n-Go (Class IIa)

Trajectory Guide Kits, Pak Needles, Pins, Drill Bits, adhesive Pad and Spheres (Class IIa)

Instruments and accessories (Class IIa)

Software Applications and Preloaded with Software Systems (Class IIb)

Passive Catheter Introducer (PCI) Needles (Class III)

Passive Biopsy Needle Kit (Class IIII)

AxiEM Probes and Kits (Class III)

AxiEM Shunt Kits (Class III)

Passive Optical Probes (Class III)

EM/EMT Malleable Suction Instruments (Class III)

Visualase Platform (Class IIb)

DEKRA Certification B.V.

drs. G.J. Zoetbrood
Managing Director

ing. A.A.M. Laan
Certification Manager

DEKRA Certification B.V. is Notified Body with ID no 0344

DEKRA Certification B.V. Meander 1051, 6825 MJ Arnhem P.O. Box 5185, 6802 ED Arnhem, The Netherlands
T +31 88 96 83000 F +31 88 96 83100 www.dekra-certification.com Company registration 09085396

ADDENDUM

Belonging to certificate: 3814174CE01

CE MARKING OF CONFORMITY
MEDICAL DEVICES

Image Guided Surgery Systems and Accessories

Issued to:

Medtronic Navigation, Inc.
826 Coal Creek Circle
Louisville, CO 80027
United States Of America

Cooled Laser Ablation System (Class III)

VCLAS accessories kit (Class IIa)
- Body Accessory Kit
- Visualization Stylet Kit
- Neuro Accessory Kit

Initial date: 15 July 2015
Revision date: 08 March 2018

DEKRA Certification B.V.

drs. G.J. Zoetbrood
Managing Director

ing. A.A.M. Laan
Certification Manager

DEKRA Certification B.V. is Notified Body with ID no 0344

DEKRA Certification B.V. Meander 1051, 6825 MJ Arnhem P.O. Box 5185, 6802 ED Arnhem, The Netherlands
T +31 88 96 83000 F +31 88 96 83100 www.dekra-certification.com Company registration 09085396