

# EC DESIGN-EXAMINATION CERTIFICATE

Number: 3814174DE02

**Directive 93/42/EEC on Medical devices, Annex II (4)**  
(Devices in Class III)

Manufacturer:

**Medtronic Navigation, Inc.**

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

For the product

**Surgical Instruments**

Documents that form the basis of this certificate:

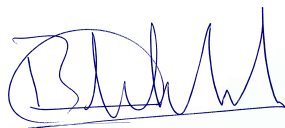
**Certification Notice 3814174CN, initially dated 15 July 2015**  
**Addendum, initially dated 1 November 2018**

DEKRA hereby declares that the design of the product(s) falling within the product category mentioned above, 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, based on an examination in accordance with Annex II (4) of this Directive. The manufacturer has implemented a quality assurance system for the above mentioned product category in accordance to the provisions of Annex II (4) of Council Directive 93/42/EEC of June 14, 1993 and is subject to periodical surveillance.

The necessary information and the reference to the relevant documentation, of the products concerned and the examinations and assessments performed, are stated in the Certification Notice which forms an integrative part of this certificate.

This certificate is valid until: 14 November 2023  
Issued for the first time: 15 July 2015  
Reissued: 08 November 2018

DEKRA Certification B.V.

A blue ink signature of the Managing Director, consisting of stylized initials and a surname.

Managing Director

A blue ink signature of J.A. van Vugt, consisting of stylized initials and a surname.

J.A. van Vugt  
Certification Manager

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

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# ADDENDUM

Belonging to certificate: 3814174DE02

1/1

## EC DESIGN-EXAMINATION MEDICAL DEVICES

Surgical Instruments

Issued to:

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

This certificate covers the following product(s):

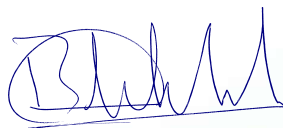
Passive Biopsy Needle Kit

Device	Model Number
Passive Biopsy Needle Kit	9733068

Initial date: 15 July 2015

Reissued: 08 November 2018

DEKRA Certification B.V.



Managing Director



J.A. van Vugt  
Certification Manager

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