

# CERTIFICATE

Number: 3814381

The management system of:

**Medtronic Navigation, Inc.**

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

including the implementation meets the requirements of the standard:

## EN ISO 13485:2016

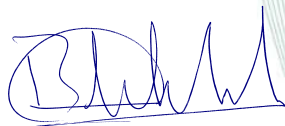
**Scope:**

Design and Development, Manufacture, Distribution, Installation and Servicing of Computer Assisted Surgical Systems Including Hardware, Application Software, Surgical Instruments, Registration Instruments, Interfaces, Image Processing Systems, Sterile Surgical Instruments (i.e. Sterile Biopsy Needles, Sterile Spheres, etc.).

This certification also includes the location as identified on the Addendum belonging to this Certificate.

Certificate expiry date: 10 August 2020  
Certificate effective date: 13 November 2018  
Certified since: 15 July 2015

DEKRA Certification B.V.

A blue ink signature of B.T.M. Holtus, the Managing Director of DEKRA Certification B.V.

B.T.M. Holtus  
Managing Director

A blue ink signature of J.A. van Vugt, the Certification Manager.

J.A. van Vugt  
Certification Manager

© Integral publication of this certificate and adjoining reports is allowed





# ADDENDUM 1/1

to Certificate 3814381

concerning the Management System of:

## Medtronic Navigation, Inc.

List of certified locations

Location	Certification scope / Activity
Medtronic Navigation, Inc. 867 Coal Creek Circle Louisville, CO 80027 USA	Design and Development, Installation and Servicing of Computer Assisted Surgical Systems Including Hardware, Application Software, Surgical Instruments, Registration Instruments, Interfaces, Image Processing Systems, Sterile Surgical Instruments (i.e. Sterile Biopsy Needles, Sterile Spheres, etc.).
Medtronic Navigation, Inc. 1480 Arthur Avenue Louisville, CO 80027 USA	Manufacture, Distribution and Servicing of Computer Assisted Surgical Systems Including Hardware, Application Software, Surgical Instruments, Registration Instruments, Interfaces, Image Processing Systems, Sterile Surgical Instruments (i.e. Sterile Biopsy Needles, Sterile Spheres, etc.).

Addendum Initial date: 15 July 2015  
Addendum Effective date: 13 November 2018