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:	Passive Biopsy Needle Kit

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 Section 4, Cert No. 3814174CE01 issued by DEKRA Certification B.V., Meander 1051, 6825 MJ, Arnhem, The Netherlands on 28 June 2018. Valid from 15 July 2015 until 08 July 2023.

EC Design-Examination Certificate under Annex II, Section4, Cert No. 3814174DE02 issued by DEKRA Certification B.V., Meander 1051, 6825 MJ, Arnhem, The Netherlands on 08 November 2018. Valid from 15 July 2015 until 14 November 2023.

EN ISO 13485:2016, Cert No. 3814381 issued by DEKRA Certification B.V., Meander 1051, 6825 MJ, Arnhem, The Netherlands on 10 February 2020. Valid from 15 July 2015 until 10 August 2020.

.

Digitally signed by Cucerenco Olesea
Date: 2020.05.04 13:17:46 EEST
Reason: MoldSign Signature
Location: Moldova

Applied Standards:

Number	Title
EN ISO 14971:2012	Medical devices – Application of risk management to medical devices
EN ISO 13485:2016	Medical devices – Quality management system – Requirements for regulatory purposes
EN ISO 10993-1:2009/AC:2010	Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process
EN ISO 10993-7:2008/AC:2009	Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals
ASTM A967/A967M:2017	Standard Specification for Chemical Passivation Treatments for Stainless Steel Parts
EN ISO 15223-1:2016	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General
EN 1041:2008	Information supplied by the manufacturer of medical devices
EN ISO 11135-1:2007	Sterilization of health care products- Ethylene oxide – Part 1: Requirements for development, validation, and routine control of a sterilization process for medical devices
EN ISO 11607-1:2009	Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems
EN ISO 11607-2:2006	Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes

Rishi Sinha 04-Mar-2020

(Signature) (Date)

Rishi Sinha
Senior Manager, Regulatory Affairs
Louisville, CO 80027
USA

REF	DESCRIPTION	CE Class	Rule	Pathway	CE Date	GMDN
9733068	Passive Biopsy Needle Kit	III	6	Annex II.4	7-15-2015	38563