# EC CERTIFICATE

Number: 2096404CE03

## Full Quality Assurance System

**Directive 93/42/EEC on Medical devices, Annex II excluding (4)**
(Devices in Class IIa, IIb or III and Devices in Class I with measuring function and in sterile condition)

Manufacturer:

## Medtronic, Inc.

**710 Medtronic Parkway NE**
**Minneapolis, MN 55432**
**United States Of America**

Digitally signed by Cucerenco Olesea
Date: 2020.05.04 13:31:04 EEST
Reason: MoldSign Signature
Location: Moldova

For the product category(ies)

**Neuro Surgical Implants, Hydrocephalus Treatment Implants, Orthopaedic Surgical Implants, External Drainage Products, Spinal Access Systems, Cranio-Maxilio-Facial (CMF) Products 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 2096404CN, initially dated 10 April 2007**
**Addendum, initially dated 16 March 2016**

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, that covers the aspects of manufacture concerned with the conformity of the devices with metrological requirements and with securing and maintaining sterile conditions, for the above mentioned product category in accordance to the provisions of Annex II 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: 1 May 2024 Revised: 1 May 2019
Issued for the first time: 27 December 2012 Reissued: 1 May 2019

DEKRA Certification B.V.

B.T.M. Holtus
Managing Director

J.A. van Vugt
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: 2096404CE03 

# CE MARKING OF CONFORMITY
## MEDICAL DEVICES

Neuro Surgical Implants, Hydrocephalus Treatment Implants, Orthopaedic Surgical Implants, External Drainage Products, Spinal Access Systems, Cranio-Maxilio-Facial (CMF) Products and Accessories

Issued to:

**Medtronic, Inc.**
**710 Medtronic Parkway NE**
**Minneapolis, MN 55432**
**United States Of America**

This certificate covers the following location(s):

| Location | Certification scope/Activity |
|---|---|
| Medtronic Neurosurgery<br>125 Cremona Drive<br>Goleta, CA 93117<br>USA | Design and development and manufacture of Neuro, Orthopedic and Cranial Implants and Instruments/Tools, Hydrocephalus Treatment Implants, External Drainage Products, Spinal Access Systems, Systems and their Instruments/Tools |

Initial date: 16 March 2016
Revision date: 1 May 2019

DEKRA Certification B.V.

B.T.M. Holtus
Managing Director

J.A. van Vugt
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