EC DESIGN-EXAMINATION CERTIFICATE

Number: 2096404DE02

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

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

Digitally signed by Cucerenco Olesea
Date: 2020.05.04 13:30:24 EEST
Reason: MoldSign Signature
Location: Moldova

For the product

Catheters for Single Use

Documents, that form the basis of this certificate:

Certification Notice 2096404CN, initially dated 10 April 2007
CE Marking of Conformity 2096404CE03
Addendum, initially dated 27 December 2012

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: 1 May 2024
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
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ADDENDUM

Belonging to certificate: 2096404DE02

EC DESIGN-EXAMINATION
MEDICAL DEVICES

Catheters for Single Use

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 125 Cremona Drive Goleta, CA 93117 USA	Design and manufacturing of External Drainage and Monitoring (EDM) Ventricular Catheters and Catheter Kits

This certificate covers the following product(s):

External Drainage and Monitoring (EDM) Ventricular Catheters and Catheter Kits
Becker EDM Ventricular Catheter, Models: 27156, 27384, 46115, 96115
EDM Ventricular Catheter, Models: 26020, 26057, 27637, 27695, 27703, 27705, 27842, 46118, 96118

Initial date: 27 December 2012
Revision date: 1 May 2019

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