EC DESIGN-EXAMINATION CERTIFICATE

Number: 2096404DE08

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

For the product

Catheters for Single Use

Documents, that form the basis of this certificate:

Certification Notice 2096404CN, initially dated 10 April 2007
Addendum, initially dated 27 October 2015

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 October 2015
Reissued: 1 May 2019

Digitally signed by Cucerenco Olesea
Date: 2020.05.04 13:30:33 EEST
Reason: MoldSign Signature
Location: Moldova

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: 2096404DE08

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 CSF Ventricular Catheters, Opus Ventricular Catheters, CSF Cardiac/Peritoneal Catheters, CSF Flow Control Shunt Kits and Assemblies, and Rivulet Ventricular Catheters

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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 product(s):

CSF Ventricular Catheters

Models			
41101	41103	41115	41207
41308	41404	41405	41406
41407	41408	41409	91503
99102	27240	5005-A	5005-B
5005-C	5005-E	5005-F	5005-G
5005-H	5005-I	9025	22082-F
22082-G	22082-H	22082-I	24004-B
27165	27211	24154	27065 A
27065 B	27065 C	27065 D	27065 E
27065 F	27065 G	27065 H	27065 K
27065 L	27251	24094	27600
27298	27607 A	27607 B	27607 C
27607 D			

Opus Ventricular Catheters

Models	
41501	41503

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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 product(s): continued

CSF Cardiac/Peritoneal Catheters

Models			
43103	43111	43209	43418
9007-H	9007-L	9007-M	24010
22002 H	22002 L	22002 M	24148
25104			

Shunt Kits and Assemblies

Models			
46012	46014	46016	46022
46024	46026	46220	46222
46224	46240	46242	46244
46622	46624	46626	46642
46644	46646	24012-5	24013-1
24013-2	24013-5	25014-1	25014-2
25014-5	46871	46876	46881
46886	27820	27821	25131-1
25131-2	25131-5	25132-1	25132-2
25132-5	9040 A	9040 B	9040 C
9040 D	9040 E	9040 F	9003 A
9003 B	9003 C	9003 D	9003 E
9003 F	22011 LL	22011 L	22011 M

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ADDENDUM

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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 product(s): continued

Rivulet Ventricular Catheters

Models
41701

Ventricular/Ventriculostomy Reservoirs

Models			
20028	9013A	9013B	9013F
21029	44000	44010	44102
44103	44104	44105	44108
44111	44113	44100	44101
44201	44211	20038A	20038B
20038C	20038D	22101A	22101B
22101C	22101D	22101E	24106A
24106B	24106C	24106D	24106E
23038A	23038B	23038C	23038D
23038E			

Initial date: 27 October 2015
Revision date: 1 May 2019

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