Revision History page

DoC No.: 10833523DOC (CE-050)		
Article 12 MDD 93/42/EEC for Systems and Procedure Packs Declaration **MEDTRONIC NEUROSURGERY** **CSF Flow Control Shunt Kits and Assemblies**	Revised by: Gilbert Laim 08-NOV-2018 Gilbert Laim	
Revision History Description	**Revision**	**Implementation Date**
CSF-shunt kits, models 22050B, 24102LL, 240102L, 24102M	Initial	September 24, 2002
Addition of model numbers 27820, 27821	A	February 3, 2006
Addition and removal of kit models and update to EC Certificates.	B	October 15, 2010
Updated "Article 12 MDD 93/42/EEC for Systems and Procedure Packs Declaration" statement to appropriately address compliance. Added 9013-A, -B, -C, -F, and –G, 25131-4 Removed obsoleted PN: 27738-AL, -AM, and -AH	C	November 5, 2010
Certificate Q1N 10 08 39709 675 replaces Q1N 07 10 39709 512.	D	December 20, 2010
Certificate 2096404CE03 replaces G1 09 09 39709 609 Certificate 2096404CE03 replaces 2096404CE03	E	February 1 ,2011
-Updated EC Certificate No. G7 08 05 39709 468 to 2096404DE08 per Certificate Renewal (RAE00523). -Inclusion of EC Certificate No. 2096404DE102096404DE10 (RAE00247) and C/N's 2120-125, 2120-925, 27588. -Addition of specific references to CE Marked Catalog Numbers for each Kit Model Number. -Revised heading of DoC CE-050 from Declaration of Conformity to Article 12 MDD 93/42/EEC for Systems and Procedure Packs Declaration. -Removed Attachment 2 and reference to 2096404CE03 from "QS Certificate Section".	F	August 11, 2011
-Updated Certificate No. G2S 06 01 39709 434 to 2096404CE03. -Added Reference to 2096404CE03 to Class IIa/IIb C/Ns under Attachment 1. -Revised 10147-1 to 10147. Currently EC Certificate No. 2096404DE08 lists 10147 which includes both C/N variations 10147-1 and 10147-2.	G	August 22, 2011
Revised 42506 to 42546 (Typographical error correction)	H	December 20, 2011
Incorporated into new template (FORM-SOP-RA-05-7). There were no changes to the content; the new template incorporates minor differences such as a controlled form number and minor terminology changes.	I	January 24, 2012
-Replace the following Part Numbers (P/Ns): 10028/10028-1, 10147 and 10149 with Catalog Numbers (C/Ns) 41101, 41207 and 43209 respectively. The P/Ns and C/Ns are CE Marked via EC Certificate No. 2096404DE08. For clarity, the C/Ns will be provided in place of the P/Ns to provide traceability to individual CE Marked labelling components. Each P/N is physically included within each C/N as documented by the respective Bill of Materials (BOMs). -Removed component P/Ns referenced under Kit Model No. 276124 for consistency with other Kit Model Nos.	J	May 31, 2012
Replaced Kit number 9013-X's component 22012 with 5005-X according to the size of the catheters.	K	June 8,2012
Removed C/N 23673 - moved to CE-012	L	March 14, 2013
Removed 25014-4, 276121, 276122, 276124, & 276125 due to obsolescence, update to reflect DEKRA dossier transfers, general C/N format clean-up	M	April 15, 2013

Correction of validity date	N	July 26, 2013
Addition of C/N 27663 (moved from CE-012), update ISO 13485 certificate number, updated product descriptions	O	November 13, 2013
Removed 25041-1, -2, & -5 (Class III per CE-002), removed blunt needle from 22050 B (included in 23067), removed inactive C/N 9013 C, D, E, G, 24106 F, G, H, 25042, 27663, 46070, 46075, 46080, & 46085; added C/N 27302, 27303, 27304, 46440, 46441, 46442, 46141 as these products have been converted to ART 12 from Class III	P	October 30, 2014
Update DoC to reflect the updated Annex II and Annex V EC Certificate	Q	February 4, 2016
Update DoC to reflect DEKRA as notified body and new Annex II EC Certificate	R	June 15, 2016
Remove CSF Ventricular reservoir catalogue numbers 9013 A, 9013 B, 9013 F. These C/Ns are currently covered in CE-002.	S	June 16, 2016
Update to reflect the new revision of DoC template FORM-SOP-RA-05-5 Rev F	1	02-DEC-2016
Correct legal manufacturer address.	2	15-Mar-2017
Remove 23038 A, 23038 B, 23038 C, 23038 D, 23038 E from the DoC due to wrongly affixed CE Mark on Label and update ISO Certificate number	3	15-May-2018
Remove 27824 and 28725 from DoC	4	15-June-2018
Move models neonatal ventricular reservoir with catheter (24106 A, 24106 B, 24106 C, 24106 D, 24106 E, 23038 A, 23038 B, 23038 C, 23038 D, 23038 E), Strata unitized shunts (46871, 46876, 46881, 46886, 27820, 27821), Delta shunt kit (25131-1, 25131-2, 25131-5, 25132-1, 25132-2, 25132-5), CSF flow control shunt kit (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), and innervision catheter 27298) to CE002; Move models Strata NSC LP shunt 44420, 44421, 44430 to CE007; Remove model 20026 A-M, 27787, 27786, 25131-4.	5	08-AUG-2018
Remove model 22050 B from DoC	6	08-Nov-2018

Article 12 MDD 93/42/EEC for Systems and Procedure Packs Declaration

Manufacturer:	Medtronic Inc. 710 Medtronic Parkway NE Minneapolis MN 55432 USA
EC Representative:	Medtronic B.V. Earl Bakkenstraat 10 6422 PJ Heerlen The Netherlands
Description of device concerned:	CSF Flow Control Shunt Kits and Assemblies, External Drainage and Monitoring Systems, Neuroendoscope Kits
Catalog Number:	See Attachment 1
EC Certificate:	2096404CE03
EC Quality System Certificate:	3820069 2096404CE03
Notified Body:	DEKRA Certification B.V. Meander 1051, 6825 MJ Arnhem The Netherlands
Notified Body Identification Number:	0344

Statement:

Medtronic Inc. 710 Medtronic Parkway, Minneapolis, USA declares that the below procedure packs fulfill the requirements of article 12 of the 93/42/EEC[1] medical device directive and can be placed on the EU market.

I, the undersigned, hereby declare that:

- it has verified the compatibility of the devices included in these procedure packs
- it is responsible for assembling, packaging and sterilizing these packs in agreement with sterilization instructions provided by the original device manufacturers and for supplying adequate instruction for use to users
- the individual components of the procedure pack bear the CE marking
- these activities are subjected to appropriate methods of internal control and inspection.

This declaration applies to all procedure packs specified above distributed from the signature date forward.

Place: Medtronic Neurosurgery
125 Cremona Drive
Goleta, CA 93117 USA

08-Nov-2018

Identification of signer: Name : Xiaojian Sun
Function: Manager, Regulatory Affairs
Entity : Medtronic Neurosurgery

Signature and Date:

[1] Including amendments issued in the years following

Attachment 1

The below procedure pack (kit) model numbers are covered under this Article 12 Statement Declaration:

Pack (Kit) Model Number	Product Description	Components Included	CE Marked Catalog Number	Class	Technical File	EC Certificate (If Applicable)
20034	EDMS Ventricular Drainage Kit	EDM Catheter	46118	III	CE-012	2096404DE02
		EDMS Drainage bag	46124	I, sterile	CE-013	2096404CE03
		EDM Patient connection line	46126	I, sterile	CE-013	2096404CE03
26040	External Drainage and Monitoring Kit	Becker EDMS	46129	I, sterile	CE-013	2096404CE03
		EDM Ventricular Catheter	46118	III	CE-012	2096404DE02
27297	Ventricular Drainage and Monitoring Kit	EDM Drainage Assembly	46422	I, sterile	CE-013	2096404CE03
		EDM Ventricular Catheter	46118	III	CE-012	2096404DE02
		EDM Drainage Bag	46124	I, sterile	CE-013	2096404CE03
46141	Ventricular Drainage and Monitoring Kit, 5 pack	EDM Drainage Assembly	46422	I, sterile	CE-013	2096404CE03
		EDM Ventricular Catheter	46118	III	CE-012	2096404DE02
		EDM Drainage Bag	46124	I, sterile	CE-013	2096404CE03
27581	Exacta and EDM Ventricular Catheter Kit	Exacta System	46700	I, sterile	CE-013	2096404CE03
		EDM Ventricular Catheter	46118	III	CE-012	2096404DE02
25030	External Drainage and Monitoring Ventricular Drainage Kit	EDMS Catheter	46115	III	CE-012	2096404DE02
		Becker Drainage Bag	46124	I, sterile	CE-013	2096404CE03
		EDM Patient Connection Line Assembly	46126	I, sterile	CE-013	2096404CE03
27811	Becker EDM System w/EDM Catheter	Becker EDM System	27702	I, sterile	CE-013	2096404CE03
		EDM Ventricular Catheter	46118	III	CE-012	2096404DE02
27795	Exacta EDM System w/ EDM Catheter	Exacta EDM System	46705	I, sterile	CE-013	2096404CE03
		EDM Ventricular Catheter	46118	III	CE-012	2096404DE02
46915	Duet External Drainage and Monitoring System, Interlink Injection Sites, Ventricular Catheter	Duet External Drainage and Monitoring System, Interlink Injection Sites	46913	I, sterile	CE-013	2096404CE03
		EDM Ventricular Catheter	46118	III	CE-012	2096404DE02
46916	Duet External Drainage and Monitoring System, SmartSite Injection Sites, Ventricular Catheter	Duet External Drainage and Monitoring System, SmartSite Injection Sites	46914	I, sterile	CE-013	2096404CE03
		EDM Ventricular Catheter	46118	III	CE-012	2096404DE02
46917	Duet External Drainage and Monitoring System, Interlink Injection Sites, Lumbar Catheter	Duet External Drainage and Monitoring System, Interlink Injection Sites	46913	I, sterile	CE-013	2096404CE03
		EDM Lumbar Catheter	46419	III	CE-021	2096404DE01
2120-125	Innervision Endoscopic	Innervision Ventricular Catheter, 15 cm	27240	III	CE-002	2096404DE08

Pack (Kit) Model Number	Product Description	Components Included	CE Marked Catalog Number	Class	Technical File	EC Certificate (If Applicable)
	Shunt Placement Kit with Ventricular Catheter	NeuroPEN Endoscope	2120-025	III	CE-204	2096404DE102096404DE10
2120-925	Innervision Endoscopic Shunt Placement Kit with BioGlide Catheter	Innervision Ventricular Catheter with BioGlide, Standard, Translucent, with Barium Stripe, 15cm	99102	III	CE-002	2096404DE08
		NeuroPEN Endoscope	2120-025	III	CE-204	2096404DE102096404DE10
27588	Innervision Endoscopic Shunt Placement Kit with Slotted Ventricular Catheter	Innervision Slotted Ventricular Catheter, Large, Barium Impregnated, 15cm	27600	III	CE-002	2096404DE08
		NeuroPEN Endoscope	2120-025	III	CE-204	2096404DE102096404DE10
27302	External Drainage and Monitoring Lumbar Kit	EDM Lumbar Catheter	46419	III	CE-021	2096404DE01
		EDM Drainage Assembly	46422	I, sterile	CE-013	2096404CE03
		EDM Drainage Bag	46124	I, sterile	CE-013	2096404CE03
27303	External Drainage and Monitoring Lumbar Kit	External Drainage and Monitoring Lumbar Catheter	46420	III	CE-021	2096404DE01
		Drainage Patient Connection Line	46126	I, sterile	CE-013	2096404CE03
		EDM Drainage Bag	46124	I, sterile	CE-013	2096404CE03
27304	External Drainage and Monitoring Lumbar Kit	EDM Lumbar Catheter	46419	III	CE-021	2096404DE01
		Drainage Patient Connection Line	46126	I, sterile	CE-013	2096404CE03
		EDM Drainage Bag	46124	I, sterile	CE-013	2096404CE03
46440	External Drainage and Monitoring Lumbar Kit, 5 Pack	EDM Lumbar Catheter	46419	III	CE-021	2096404DE01
		EDM Drainage Assembly	46422	I, sterile	CE-013	2096404CE03
		EDM Drainage Bag	46124	I, sterile	CE-013	2096404CE03
46441	External Drainage and Monitoring Lumbar Kit, 5 Pack	External Drainage and Monitoring Lumbar Catheter	46420	III	CE-021	2096404DE01
		Drainage Patient Connection Line	46126	I, sterile	CE-013	2096404CE03
		EDM Drainage Bag	46124	I, sterile	CE-013	2096404CE03
46442	External Drainage and Monitoring Lumbar Kit, 5 Pack	EDM Lumbar Catheter	46419	III	CE-021	2096404DE01
		Drainage Patient Connection Line	46126	I, sterile	CE-013	2096404CE03
		EDM Drainage Bag	46124	I, sterile	CE-013	2096404CE03