

Revision History

		DoC No.: 10833520DOC (CE-002)
EC DECLARATION OF CONFORMITY MEDTRONIC NEUROSURGERY Cardiac-Peritoneal and Ventricular Catheters & Shunts		 Revised by: Gilbert Laim 1-Nov-2018
Revision History Description	Revision	Implementation Date
CSF-shunt kits, models 9013-D, 9013-E, 2120-125, 2120-925, 20026A-L, 20026A-M, 20026A-H, 20026B-L, 20026B-M, 20026B-H, 20026C-L, 20026C-M, 20026C-H, 20026D-L, 20026D-M, 20026D-H, 20026E-L, 20026E-M, 20026E-H, 20026F-L, 20026F-M, 20026F-H, 22060LL, 22060L, 22060M, 22085L, 25014-4, 25128-1, 25128-2, 25128-4, 27233LL, 27233L, 27233M, 24106A, 24106B, 24106C, 24106D, 24106E, 24106F, 24106G, 24106H, 27298, 27278L, 27278M, 46885, 46875, 46880, 46870, 20034, 23038A, 23038B, 23038C, 23038D, 23038E, 24052, 26040, 27295, 27296, 27297, 27581, 27588, 276121, 276122, 276124, 276125, 27650, 27651, 27693, 27694, 25030, 27665, 27637	Initial	October 31, 2002
Additional model number 27738	A	September 25, 2003
Correction of model number 27738 – added suffix 27738AL, 27738AM, 27738AH	B	October 15, 2003
Additional model number 46085, 46080, 46075, 46070	C	April 9, 2004
Additional model numbers 27803, 27804	D	July 22, 2004
Additional model numbers 27820, 27821, 44420, 44421, 44430	E	April 16, 2007
Correction to listed products	F	April 28, 2010
Correction to listed products per new EC certificate number G7 08 05 39709 468, CSF shunt kits moved to CE-023, update standards and format	G	June 15, 2010
Certificate G1 11 01 39709 702 replaces G1 09 09 39709 609	H	February 1, 2011
-Updated Attachment 1 Standards List according to Essential Requirements Checklist dated February 14, 2011. -Updated Attachment 2 Product List (C/N's currently listed in Cert. No. G7 08 05 39709 468, to be revised via RAE00523 Cert. Renewal) • Added C/N: 25014-4 • Removed Obsolete C/N: 21027-A, -B, 22012-D, -E, -F, -G, -H, 22082-J, -K, 27118, 20009, 24004-A, 27120, 27351, 5005-D, 27065-P, -U, 27522-A, -B, -C, -D, -E, -F, 27802-A, -B, -C, -D, -E, -F, -G, -H, -J, 27046-A, -B, 27277-L, -M, -H, 21020 A-L, A-H, B-L, B-H, C-L, C-M, C-H, 27745, 96012, 96014, 96016, 96022, 96024, 96026, 46312, 46314, 46316, 46612, 46614, 46616, 9015-L, -M, -H, , 20029, 22056 A-L, A-M, B-L, B-M, 24012-1, -2, 24090 A-1, A-2, A-5, B-1, B-2, B-5, 24116 (all variants), 24140 (all variants), 24150-L, -M, -H, 25022 -LL, -L, -M, 26093-L, -M, 27142-1, -2, -5, 27281-1, -2, -4, -5, 27409 (all variants), 27444-L, -M, -H, 27524 A-L, A-M, A-H, 27046C, 41712, 41713 and 41714. • Removed to CE-004: 9013-A, -B, -C, -F, -G, 9042-A, -B, -C, -D and 20028.	I	February 14, 2011
Updated EC Certificate No. G7 08 05 39709 468 to G7 11 07 39709 744 per Certificate Renewal (RAE00523).	J	August 8, 2011

Revised C/Ns for consistency with EC Cert (10147, 10253, 10410, 13253, 10027, 10149) Reincorporated C/Ns: 9013-A, -B, -C, -F, -G, 9042-A, -B, -C, -D and 20028 and added 9042-G per EC Cert. Added Shunt Kit Ventricular Catheter to Description of device concerned for consistency with Attachment 2. Removed obsolete C/N 27065N, 25014-4. Note: C/N 5005-J & 22082-J are listed in EC Cert, however they are obsolete.		
Update DoC to new template (FORM-SOP-RA-05-5 Rev B).	K	March 14, 2012
Updated to current DoC template and to reflect Notified Body change to DEKRA	L	November 19, 2015
Removed component number 10147,10253,10410,13253,10028-1,10028-2,10027,10149 from the model list. Addition of 21029,44000,44010,44102,44103,44104,44105,44108,44111,44113,44100,44101,44201,44211,20038A, 20038B, 20038C, 20038D, 22101A, 22101B, 22101C, 22101D, 22101E according to DEKRA approval 3816719 TDR25 R0. Update to reflect the new revision of DoC template FORM-SOP-RA-05-5 Rev F	1	06-Dec-2016
Add in New StrataMR unitized shunt models 46975 and 46985 according to DEKRA approval 3816392 TDR21 R3. Correct Legal manufacturer address.	2	17-Jan-2017
Remove StrataMR unitized shunt models 46975 and 46985. Update GMDN codes.	3	27-Feb-2017
Addition of 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)	4	07-Aug-2018
Remove obsolete models 22012 A, 22012 B, 22012 C, 27065 J, 27065 M, 27065 R, 27065 T, 27501, 27771, 27010, 21020 A-M, 21020 B-M, 41704, 41705, 41706, 41707, 41708, 41709, 41710, 41711, 41715, 9013 C, 9013 G, 9042 A, 9042 B, 9042 C, 9042 D, 9042 G, 27274	5	31-Oct-2018

EC Declaration of Conformity

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 Ventricular Catheters
Opus Ventricular Catheters
CSF Cardiac/Peritoneal Catheters
Shunt Kits and Assemblies

Rivulet Ventricular Catheters
Ventricular/Ventriculostomy reservoirs

Catalog Number See Attachment 1
Variants See Attachment 1

Classification Class III
Rule Rule 8

Conformity Assessment route Annex II

EC Certificates 2096404DE08, 2096404DE07, 2096404CE03

Notified Body: DEKRA Certification B.V.
Meander 1051
6825 MJ Arnhem
The Netherlands

Notified Body Identification 0344
Number:

Statement:

We, Medtronic, declare under our sole responsibility that the Medical Device(s) categories specified above and provided with the CE marking, meet the provisions of the EC Directive 93/42/EEC¹ which apply to them.

This declaration is supported by the EC Quality System Certificate(s) according to the provisions of relevant Annex(es) of above Directive. This declaration applies to all devices specified above distributed from the signature date forward.

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

Identification of signatory:

Name : Hebe Sun
Function: Manager, Regulatory
Affairs
Entity : Medtronic Neurosurgery

Signature and Date



Nov 1, 2018

¹ Including amendments issued in the years following

Attachment 1

The below catalog numbers (C/Ns) are covered by this Declaration of Conformance.

CSF Ventricular Catheters

Catalog Number	Description	Sterility	Class	Rule	Annex	GMDN
41101	FP-VENT CATH,STD,W/STY&RA CLIP	Sterile	III	8	II	61376
41103	FP-VENT CATH,15CM,STD,PLIANT	Sterile	III	8	II	61376
41115	FP-VENT CATH,TRANS,W/ST&RACLIP	Sterile	III	8	II	61376
41207	FP-VENT CATH,SML,W/STY&RA CLIP	Sterile	III	8	II	61376
41308	FP-CSF VENT CATHETER, FLANGED	Sterile	III	8	II	61376
41404	FP-VENT CATH W/SNAP BASE, 4CM	Sterile	III	8	II	61376
41405	FP-VENT CATH W/SNAP BASE, 5CM	Sterile	III	8	II	61376
41406	FP-VENT CATH W/SNAP BASE, 6CM	Sterile	III	8	II	61376
41407	FP-VENT CATH W/SNAP BASE, 7CM	Sterile	III	8	II	61376
41408	FP-VENT CATH W/SNAP BASE, 8CM	Sterile	III	8	II	61376
41409	FP-VENT CATH W/SNAP BASE, 9CM	Sterile	III	8	II	61376
91503	[NG]FP-BG VENTRICULAR CATHETER	Sterile	III	8	II	32585
99102	[NG]FP-CATH/VENT,INNERVISON BIO	Sterile	III	8	II	32585
27240	FP-CATH, VENT/INNERVISION	Sterile	III	8	II	61376
5005 A	VENT CATH,STD, RA, 7CM	Sterile	III	8	II	61376
5005 B	VENT CATH,STD, RA, 9CM	Sterile	III	8	II	61376
5005 C	VENT CATH,STD, RA, 11CM	Sterile	III	8	II	61376
5005 E	VENT CATH,STD, RA, 5CM	Sterile	III	8	II	61376
5005 F	VENT CATH,STD, RA, 4CM	Sterile	III	8	II	61376
5005 G	VENT CATH,STD, RA, 6CM	Sterile	III	8	II	61376
5005 H	VENT CATH,STD, RA, 10CM	Sterile	III	8	II	61376
5005 I	VENT CATH,STD, RA, 8CM	Sterile	III	8	II	61376
9025	VENT/CATH W/EXTRA LENGTH MARKR	Sterile	III	8	II	61376
22082 F	SNAP SHNT,V-CATH,STD,B.I. 10CM	Sterile	III	8	II	61376
22082 G	SNAP SHNT,V-CATH,STD,B.I. 11CM	Sterile	III	8	II	61376
22082 H	SNAP SHNT,V-CATH STD B.I.6.5CM	Sterile	III	8	II	61376
22082 I*	SNAP SHNT,V-CATH,STD B.I.5.5CM	Sterile	III	8	II	61376
24004 B	SNP-ASY,VNTRC RES BASE,BH,3.CM	Sterile	III	8	II	61376
27165	INNERVISION VENTRICULAR CATH	Sterile	III	8	II	61376
27211	SLOTTED VENT/CATHETER, 15CM	Sterile	III	8	II	61376
24154	V-CATH,STD,TRANS W/STRIPE,23CM	Sterile	III	8	II	61376
27065 A	[NG]INNERVSN V-CTH,SNP ASSY 4CM	Sterile	III	8	II	61376
27065 B	[NG]INNERVSN V-CTH,SNP ASSY 5CM	Sterile	III	8	II	61376
27065 C	[NG]INNERVSN V-CTH,SNP ASSY 6CM	Sterile	III	8	II	61376
27065 D	[NG]INNERVSN V-CTH,SNP ASSY 7CM	Sterile	III	8	II	61376
27065 E	[NG]INNERVSN V-CTH,SNP ASSY 8CM	Sterile	III	8	II	61376
27065 F	[NG]INNERVSN V-CTH,SNP ASSY 9CM	Sterile	III	8	II	61376

Catalog Number	Description	Sterility	Class	Rule	Annex	GMDN
27065 G	[NG]INNERVSN V-CTH,SNP ASSY10CM	Sterile	III	8	II	61376
27065 H	[NG]INNERVSN V-CTH,SNP ASSY11CM	Sterile	III	8	II	61376
27065 K	[NG]INNERVSN V-CTH,SNP ASSY5.5CM	Sterile	III	8	II	61376
27065 L	[NG]INNERVSN V-CTH,SNP ASSY6.5CM	Sterile	III	8	II	61376
27251	V-CATH,SML,B.I. W/8MM FLW HOLDS	Sterile	III	8	II	61376
24094	V-CATH,W/SNAP ASSY V-RES BASE	Sterile	III	8	II	61376
27600	INNERVISION SLOTTED V-CATH 15	Sterile	III	8	II	61376
27298	Innervision Ventricular Catheter w/ snap base	Sterile	III	8	II	61376
27607 A	CATH, VENT, RA, STD 4 CM	Sterile	III	8	II	61376
27607 B	CATH, VENT, RA, STD 5 CM	Sterile	III	8	II	61376
27607 C	CATH, VENT, RA, STD 6 CM	Sterile	III	8	II	61376
27607 D	CATH, VENT, RA, STD 7 CM	Sterile	III	8	II	61376

Opus Ventricular Catheters

Catalog Number	Description	Sterility	Class	Rule	Annex	GMDN
41501	FP-OPUS VENT CATH, SMALL	Sterile	III	8	II	32585
41503	FP-OPUS VENT CATH, STANDARD	Sterile	III	8	II	32585

CSF Cardiac-Peritoneal Catheters

Catalog Number	Description	Sterility	Class	Rule	Annex	GMDN
43103	FP-CSF-C/P CATH,BI,STD	Sterile	III	8	II	61159
43111	FP-CSF-C/P CATH,TRANS,STD	Sterile	III	8	II	61159
43209	FP-CSF-C/P CATH,BI,SMALL	Sterile	III	8	II	61159
43418	FP-CSF-CARD CATH,REDUCED TIP	Sterile	III	8	II	61159
9007 H	C/P CATH,STD,90CM,CLS PRS,HI	Sterile	III	8	II	61159
9007 L	C/P CATH,STD,90CM,CLS PRS, LOW	Sterile	III	8	II	61159
9007 M	C/P CATH,STD,90CM,CLS PRS, MED	Sterile	III	8	II	61159
24010	C/P CATH, STD,120CM,CLSD,SLITS	Sterile	III	8	II	61159
22002 H	CSF C/P CATHETER CLOSING PRE/H	Sterile	III	8	II	61159
22002 L	CSF C/P CATHETER CLOSING PRE/L	Sterile	III	8	II	61159
22002 M	CSF C/P CATHETER CLOSING PRE/M	Sterile	III	8	II	61159
24148	C/P CATHETER, STD, 110CM	Sterile	III	8	II	61159
25104	CATH,C/P,STD,TRANS,RAD STRP,90	Sterile	III	8	II	61159

Shunt Kits and Assemblies

Catalog Number	Description	Sterility	Class	Rule	Annex	GMDN
46012	FP-UNI SHUNT KIT, SML, LOW	Sterile	III	8	II	45694
46014	FP-UNI SHUNT KIT, SML, MED	Sterile	III	8	II	45694

Catalog Number	Description	Sterility	Class	Rule	Annex	GMDN
46016	FP-UNI SHUNT KIT, SML, HIGH	Sterile	III	8	II	45694
46022	FP-UNI SHUNT KIT, REG, LOW	Sterile	III	8	II	45694
46024	FP-UNI SHUNT KIT, REG, MED	Sterile	III	8	II	45694
46026	FP-UNI SHUNT KIT, REG, HIGH	Sterile	III	8	II	45694
46220	FP-SHUNT KIT, US, LOW-LOW, 4CM	Sterile	III	8	II	45694
46222	FP-SHUNT KIT, US, LOW, 4CM	Sterile	III	8	II	45694
46224	FP-SHUNT KIT, US, MED, 4CM	Sterile	III	8	II	45694
46240	FP-CSF-FLW CTRL SHNT KIT,US,LL	Sterile	III	8	II	45694
46242	FP-CSF-FLW CTRL SHNT KIT,US LP	Sterile	III	8	II	45694
46244	FP-CSF-FLW CTRL SHNT KIT,US,MP	Sterile	III	8	II	45694
46622	FP-CSF-SHNT ASSY,FLW-CTRL/V LP	Sterile	III	8	II	61123
46624	FP-CSF-SHNT ASSY,FLW CTRL/V ME	Sterile	III	8	II	61123
46626	FP-CSF-SHNT ASSY,FLW CTRL/V HI	Sterile	III	8	II	61123
46642	FP-SHNT ASSY,CONT/REG,90CM, LP	Sterile	III	8	II	61123
46644	FP-SHNT ASSY,CONT/REG,90CM, MP	Sterile	III	8	II	61123
46646	FP-SHNT ASSY,CONT/REG,90CM, HP	Sterile	III	8	II	61123
24012-5	DELTA UNIT/SHNT, SMALL, PL 1.5	Sterile	III	8	II	45694
24013-1	DELTA UNIT/SHNT REGULAR,PL 1.0	Sterile	III	8	II	45694
24013-2	DELTA UNIT/SHNT REGULAR,PL 2.0	Sterile	III	8	II	45694
24013-5	DELTA UNIT/SHNT REGULAR,PL 1.5	Sterile	III	8	II	45694
25014-1	DELTA,UNI/SHNT KIT,SML,PL 1.0	Sterile	III	8	II	45694
25014-2	DELTA,UNI/SHNT KIT,SML,PL 2.0	Sterile	III	8	II	45694
25014-5	DELTA,UNI/SHNT KIT,SML,PL 1.5	Sterile	III	8	II	45694
46871	Strata II Unishunt small	Sterile	III	8	II	45694
46876	Strata II Unishunt small	Sterile	III	8	II	45694
46881	Strata II Unishunt regular	Sterile	III	8	II	45694
46886	Strata II Unishunt regular	Sterile	III	8	II	45694

27820	Strata II Unishunt small	Sterile	III	8	II	45694
27821	Strata II Unishunt regular	Sterile	III	8	II	45694
25131-1	Delta shunt kit, small	Sterile	III	8	II	61123
25131-2	Delta shunt kit, small	Sterile	III	8	II	61123
25131-5	Delta shunt kit, small	Sterile	III	8	II	61123
25132-1	Delta shunt kit, regular	Sterile	III	8	II	61123
25132-2	Delta shunt kit, regular	Sterile	III	8	II	61123
25132-5	Delta shunt kit, regular	Sterile	III	8	II	61123
9040 A	CSF-Flow Control Shunt Kit, Burr Hole, 12 mm, Low Pressure	Sterile	III	8	II	61123
9040 B	CSF-Flow Control Shunt Kit, Burr Hole, 12 mm, Medium Pressure	Sterile	III	8	II	61123
9040 C	CSF-Flow Control Shunt Kit, Burr Hole, 12 mm, High Pressure	Sterile	III	8	II	61123

9040 D	CSF-Flow Control Shunt Kit, Burr Hole, 16 mm, Low Pressure	Sterile	III	8	II	61123
9040 E	CSF-Flow Control Shunt Kit, Burr Hole, 16 mm, Medium Pressure	Sterile	III	8	II	61123
9040 F	CSF-Flow Control Shunt Kit, Burr Hole, 16 mm, High Pressure	Sterile	III	8	II	61123
9003 A	CSF-Flow Control Shunt Kit, Contoured Small, Low Pressure	Sterile	III	8	II	61123
9003 B	CSF-Flow Control Shunt Kit, Contoured Small, Medium Pressure	Sterile	III	8	II	61123
9003 C	CSF-Flow Control Shunt Kit, Contoured Small, High Pressure	Sterile	III	8	II	61123
9003 D	CSF-Flow Control Shunt Kit, Contoured Regular, Low Pressure	Sterile	III	8	II	61123
9003 E	CSF-Flow Control Shunt Kit, Contoured Regular, Medium Pressure	Sterile	III	8	II	61123
9003 F	CSF-Flow Control Shunt Kit, Contoured Regular, High Pressure	Sterile	III	8	II	61123
22011 LL	CSF-Flow Control Shunt Kit, Ultra Small, Low-Low Pressure	Sterile	III	8	II	61123
22011 L	CSF-Flow Control Shunt Kit, Ultra Small, Low Pressure	Sterile	III	8	II	61123
22011 M	CSF-Flow Control Shunt Kit, Ultra Small, Medium Pressure	Sterile	III	8	II	61123

Rivulet Ventricular Catheters

Catalog Number	Description	Sterility	Class	Rule	Annex	GMDN
41701	CATHETER RIVULET VENTRICULAR	Sterile	III	8	II	32585

Ventricular/Ventriculostomy Reservoirs

Catalog Number	Description	Sterility	Class	Rule	Annex	GMDN
20028	VAD, BURR HOLE, 12MM W/V-CATH.	Sterile	III	8	II	61375
9013 A	V-RES, CONV. 12MM W/ CATH. 50 mm	Sterile	III	8	II	61375
9013 B	V-RES, CONV. 12MM W/ CATH. 60 mm	Sterile	III	8	II	61375
9013 F	V-RES, CONV. 12MM W/ CATH. 70 mm	Sterile	III	8	II	61375
21029	Ventricular Reservoir, 12 mm, Bottom Inlet	Sterile	III	8	II	61375
44000	CSF-Ventricular Port, Bottom Inlet, 16 mm, Bottom Inlet	Sterile	III	8	II	33923
44010	CSF-Ventricular Port, Bottom Inlet, 16 mm, Side Inlet	Sterile	III	8	II	33923
44102	CSF-Ventricular Reservoir, 18 mm, Side Inlet	Sterile	III	8	II	61375
44103	CSF-Ventricular Reservoir, 28 mm, Side Inlet	Sterile	III	8	II	61375
44104	CSF-Ventricular Reservoir, 28 mm, Bottom Inlet	Sterile	III	8	II	61375
44105	CSF-Ventricular Reservoir, 28 mm, Convertible, Bottom Inlet	Sterile	III	8	II	61375

Catalog Number	Description	Sterility	Class	Rule	Annex	GMDN
44108	CSF-Ventricular Reservoir, 30 mm, Side Inlet	Sterile	III	8	II	61375
44111	CSF-Ventricular Reservoir, 12 mm, Burr Hole	Sterile	III	8	II	61375
44113	CSF-Ventricular Reservoir, 12 mm, Burr Hole, Convertible	Sterile	III	8	II	61375
44100	CSF-Ventricular Reservoir, 12 mm, Convertible	Sterile	III	8	II	61375
44101	CSF-Ventricular Reservoir, 12 mm, Convertible	Sterile	III	8	II	61375
44201	CSF-Ventriculostomy Reservoir Kit, 6 mm, Regular Depth	Sterile	III	8	II	61375
44211	CSF-Ventriculostomy Reservoir Kit, 6 mm, Shallow Depth	Sterile	III	8	II	61375
20038 A	CSF-Ventricular Reservoir, 12mm with Integral Right Angle Ventricular Catheter, Intracranial Length: 20 mm	Sterile	III	8	II	61375
20038 B	CSF-Ventricular Reservoir, 12mm with Integral Right Angle Ventricular Catheter, Intracranial Length: 30 mm	Sterile	III	8	II	61375
20038 C	CSF-Ventricular Reservoir, 12mm with Integral Right Angle Ventricular Catheter, Intracranial Length: 40 mm	Sterile	III	8	II	61375
20038 D	CSF-Ventricular Reservoir, 12mm with Integral Right Angle Ventricular Catheter, Intracranial Length: 50 mm	Sterile	III	8	II	61375
22101 A	Neonate Reservoir, Flat Dome with Integral Ventricular Catheter, Small, Barium Impregnated, 3.0 cm	Sterile	III	8	II	61375
22101 B	Neonate Reservoir, Flat Dome with Integral Ventricular Catheter, Small, Barium Impregnated, 3.5 cm	Sterile	III	8	II	61375
22101 C	Neonate Reservoir, Flat Dome with Integral Ventricular Catheter, Small, Barium Impregnated, 2.5 cm	Sterile	III	8	II	61375
22101 D	Neonate Reservoir, Flat Dome with Integral Ventricular Catheter, Small, Barium Impregnated, 4.0 cm	Sterile	III	8	II	61375
22101 E	Neonate Reservoir, Flat Dome with Integral Ventricular Catheter, Small, Barium Impregnated, 2.0 cm	Sterile	III	8	II	61375
24106 A	Neonatal Ventricular Reservoir	Sterile	III	8	II	61375
24106 B	Neonatal Ventricular Reservoir	Sterile	III	8	II	61375
24106 C	Neonatal Ventricular Reservoir	Sterile	III	8	II	61375
24106 D	Neonatal Ventricular Reservoir	Sterile	III	8	II	61375
24106 E	Neonatal Ventricular Reservoir	Sterile	III	8	II	61375
23038 A	Neonate Reservoir	Sterile	III	8	II	61375
23038 B	Neonate Reservoir	Sterile	III	8	II	61375



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Catalog Number	Description	Sterility	Class	Rule	Annex	GMDN
23038 C	Neonate Reservoir	Sterile	III	8	II	61375
23038 D	Neonate Reservoir	Sterile	III	8	II	61375
23038 E	Neonate Reservoir	Sterile	III	8	II	61375

Note: * Device no longer in production. This design will be maintained from technical documentation perspective until inventory is depleted.