

	Declaration of Conformity	DoC-127 Revision Number: 112
	S1177: Regional Anaesthesia	

Legal Manufacturer: Smiths Medical ASD Inc.
6000 Nathan Lane North
Minneapolis, Minnesota 55442 USA

EU Representative: Smiths Medical Czech Republic a.s.
Olomoucká 306,
Hranice 1 - Město,
753 01 Hranice, Czech Republic

Product Tradename(s): Minipack epidural trays and kits, CorrectInject® Connector,
CorrectInject™ System safety system and components, LockIt Plus®
catheter securement device, DuraFlex® anesthesia catheter

Conformity Assessment Route: Annex II (excluding Section 4)

Notified Body: BSI Healthcare
Medical Devices Certification
Notified Body #2797

EC Certificate Number: CE 669121

Smiths Medical ASD, Inc. hereby declares under its sole responsibility that the product(s) referenced conform to the relevant provisions of the European Union Council Directive 93/42/EEC on Medical Devices (the MDD) as amended by Directive 2007/47/EC.

Authorized Signatory:

Signature: Stacy Novak

Date: 29 Dec 2019

Name: Stacy Novak

Title: Director, Regulatory Operations

Location of Signatory: Minneapolis, MN, US

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Appendix 1: Product List

Num	Catalog Number	Product Description	Manufacturing Site	GMDN Code	EU Risk Class	EU Rule
1.	100/398/000	LOSS OF RESISTANCE DEVICE	Smiths Medical International Ltd. 52 Grayhill Road Westfield Industrial Estate Cumbernauld Glasgow G68 9HQ United Kingdom	44884	Ila	2
2.	100/380/016	SINGLE-SHOT EPIDURAL PACK 16G	Smiths Medical International Ltd. 52 Grayhill Road Westfield Industrial Estate Cumbernauld Glasgow G68 9HQ United Kingdom	34842	Ila	6
3.	100/380/018	SINGLE-SHOT EPIDURAL PACK 18G	Smiths Medical International Ltd. 52 Grayhill Road Westfield Industrial Estate Cumbernauld Glasgow G68 9HQ United Kingdom	34842	Ila	6
4.	100/390/116	EPIDURAL MAXIPACK 16G	Smiths Medical International Ltd. 52 Grayhill Road Westfield Industrial Estate Cumbernauld Glasgow G68 9HQ United Kingdom	34842	IIb	7
5.	100/390/118	EPIDURAL MAXIPACK 18G	Smiths Medical International Ltd. 52 Grayhill Road Westfield Industrial Estate Cumbernauld Glasgow G68 9HQ United Kingdom	34842	IIb	7
6.	100/391/180	EPIDURAL MINIPACK 1 PAEDIATRIC 18G, 3 CLOSER LATERAL EYES	Smiths Medical International Ltd. 52 Grayhill Road Westfield Industrial Estate Cumbernauld Glasgow G68 9HQ United Kingdom	34842	IIb	7
7.	100/391/190	EPIDURAL MINIPACK SYSTEM 1 19GTERMINAL EYE	Smiths Medical International Ltd. 52 Grayhill Road Westfield Industrial Estate Cumbernauld Glasgow G68 9HQ United Kingdom	34842	IIb	7

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Num	Catalog Number	Product Description	Manufacturing Site	GMDN Code	EU Risk Class	EU Rule
8.	100/391/516	EPIDURAL MINIPACK SYSTEM 1 16GLONG NEEDLE, LATERAL EYES	Smiths Medical International Ltd. 52 Grayhill Road Westfield Industrial Estate Cumbernauld Glasgow G68 9HQ United Kingdom	34842	Ilb	7
9.	100/391/518	EPIDURAL MINIPACK SYSTEM 1 18GLONG NEEDLE, LATERAL EYES	Smiths Medical International Ltd. 52 Grayhill Road Westfield Industrial Estate Cumbernauld Glasgow G68 9HQ United Kingdom	34842	Ilb	7
10.	910/490/318	18G EPIDURAL CUSTOM PACK LAUBSCHER SWITZERLAND	Smiths Medical International Ltd. 52 Grayhill Road Westfield Industrial Estate Cumbernauld Glasgow G68 9HQ United Kingdom	34842	Ilb	7
11.	921/016/0176	CUSTOM 16G EPIDURAL PACK - ROYAL ORTHOPAEDIC HOSPITAL	Smiths Medical International Ltd. 52 Grayhill Road Westfield Industrial Estate Cumbernauld Glasgow G68 9HQ United Kingdom	34842	Ilb	7
12.	921/016/0178	16G EPIDURAL CUSTOM PACK, MANCHESTER ROYAL INFIRMARY	Smiths Medical International Ltd. 52 Grayhill Road Westfield Industrial Estate Cumbernauld Glasgow G68 9HQ United Kingdom	34842	Ilb	7
13.	921/016/0190	16G EPIDURAL LUTON & DUNSTABLEHOSPITAL	Smiths Medical International Ltd. 52 Grayhill Road Westfield Industrial Estate Cumbernauld Glasgow G68 9HQ United Kingdom	34842	Ilb	7
14.	921/016/0222	16G EPIDURAL CUSTOM KIT MANCHESTER ROYL INFIRMAR	Smiths Medical International Ltd. 52 Grayhill Road Westfield Industrial Estate Cumbernauld Glasgow G68 9HQ United Kingdom	34842	Ilb	7

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Num	Catalog Number	Product Description	Manufacturing Site	GMDN Code	EU Risk Class	EU Rule
15.	921/018/0201	18G EPIDURAL CUSTOM KIT CAROLUS HOSP NETHERLANDS	Smiths Medical International Ltd. 52 Grayhill Road Westfield Industrial Estate Cumbernauld Glasgow G68 9HQ United Kingdom	34842	IIb	7
16.	922/000/0414	CUSTOM PNB PREP PCK FOR OULU UNIVERSITY HOSPITAL	Smiths Medical International Ltd. 52 Grayhill Road Westfield Industrial Estate Cumbernauld Glasgow G68 9HQ United Kingdom	34842	IIa	6
17.	922/016/0140	16G EPIDURAL CUSTOM PACK, DERRIFORD HOSPITAL	Smiths Medical International Ltd. 52 Grayhill Road Westfield Industrial Estate Cumbernauld Glasgow G68 9HQ United Kingdom	34842	IIb	7
18.	922/016/0142	CUSTOM RA TRAY, NORTHWICK PARKHOSPITAL	Smiths Medical International Ltd. 52 Grayhill Road Westfield Industrial Estate Cumbernauld Glasgow G68 9HQ United Kingdom	34842	IIb	7
19.	922/016/0154	CUSTOM RA TRAY, ST PETER'S HOSPITAL	Smiths Medical International Ltd. 52 Grayhill Road Westfield Industrial Estate Cumbernauld Glasgow G68 9HQ United Kingdom	34842	IIb	7
20.	922/016/0161	16G EPIDURAL PACK, ABERDEEN ROYAL INFIRMARY	Smiths Medical International Ltd. 52 Grayhill Road Westfield Industrial Estate Cumbernauld Glasgow G68 9HQ United Kingdom	34842	IIb	7
21.	922/016/0163	16G EPIDURAL PACK POOLE HOSP.	Smiths Medical International Ltd. 52 Grayhill Road Westfield Industrial Estate Cumbernauld Glasgow G68 9HQ United Kingdom	34842	IIb	7

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Num	Catalog Number	Product Description	Manufacturing Site	GMDN Code	EU Risk Class	EU Rule
22.	922/016/0166	QUEEN ALEXANDRA HOSPITAL EPIDURAL PACK	Smiths Medical International Ltd. 52 Grayhill Road Westfield Industrial Estate Cumbernauld Glasgow G68 9HQ United Kingdom	34842	Ilb	7
23.	922/016/0183	16G CUSTOM EPIDURAL PACK, YSBYTY GWYNEDD HOSPITAL	Smiths Medical International Ltd. 52 Grayhill Road Westfield Industrial Estate Cumbernauld Glasgow G68 9HQ United Kingdom	34842	Ilb	7
24.	922/016/0184	16G EPIDURAL PACK, ROYAL FREE HOSPITAL	Smiths Medical International Ltd. 52 Grayhill Road Westfield Industrial Estate Cumbernauld Glasgow G68 9HQ United Kingdom	34842	Ilb	7
25.	922/016/0209	16G EPIDURAL, MANOR HOSPITAL	Smiths Medical International Ltd. 52 Grayhill Road Westfield Industrial Estate Cumbernauld Glasgow G68 9HQ United Kingdom	34842	Ilb	7
26.	922/016/0210	16G EPIDURAL, HILLIINGDON HOSP.	Smiths Medical International Ltd. 52 Grayhill Road Westfield Industrial Estate Cumbernauld Glasgow G68 9HQ United Kingdom	34842	Ilb	7
27.	922/016/0243	16G EPIDURAL CUSTOM KIT FOR BOOTS HEALTHCARE	Smiths Medical International Ltd. 52 Grayhill Road Westfield Industrial Estate Cumbernauld Glasgow G68 9HQ United Kingdom	34842	Ilb	7
28.	922/016/0257	16G EPIDURAL CUSTOM KIT, KENT & SUSSEX HOSPITAL	Smiths Medical International Ltd. 52 Grayhill Road Westfield Industrial Estate Cumbernauld Glasgow G68 9HQ United Kingdom	34842	Ilb	7

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29.	922/016/0274	16G EPIDURAL CUSTOM KIT ST GEORGE'S HOSPITAL	Smiths Medical International Ltd. 52 Grayhill Road Westfield Industrial Estate Cumbernauld Glasgow G68 9HQ United Kingdom	34842	Iib	7
30.	922/016/0301	16G EPIDURAL CUSTOM KIT FOR NORFOLK&NORWICH HOSP	Smiths Medical International Ltd. 52 Grayhill Road Westfield Industrial Estate Cumbernauld Glasgow G68 9HQ United Kingdom	34842	Iib	7
31.	922/016/0328	16G EPIDURAL KIT DERBYSHIRE ROYAL INFIRMARY	Smiths Medical International Ltd. 52 Grayhill Road Westfield Industrial Estate Cumbernauld Glasgow G68 9HQ United Kingdom	34842	Iib	7
32.	922/016/0353	16G EPIDURAL CUSTOM KIT BILLINGE HOSPITAL	Smiths Medical International Ltd. 52 Grayhill Road Westfield Industrial Estate Cumbernauld Glasgow G68 9HQ United Kingdom	34842	Iib	7
33.	922/016/0356	16g EPIDURAL CUSTOM KIT NORTH HAMPSHIRE HOSPITAL	Smiths Medical International Ltd. 52 Grayhill Road Westfield Industrial Estate Cumbernauld Glasgow G68 9HQ United Kingdom	34842	Iib	7
34.	922/016/0373	16G EPIDURAL CUSTOM KIT WEST SUFFOLK HOSPITAL	Smiths Medical International Ltd. 52 Grayhill Road Westfield Industrial Estate Cumbernauld Glasgow G68 9HQ United Kingdom	34842	Iib	7
35.	922/016/0400	16G EPIDURAL CUSTOM KIT WHITTINGTON NHS TRUST	Smiths Medical International Ltd. 52 Grayhill Road Westfield Industrial Estate Cumbernauld Glasgow G68 9HQ United Kingdom	34842	Iib	7

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Num	Catalog Number	Product Description	Manufacturing Site	GMDN Code	EU Risk Class	EU Rule
36.	922/016/0402	16G EPIDURAL CUSTOM KIT FOR EAST SURREY HOSPITAL	Smiths Medical International Ltd. 52 Grayhill Road Westfield Industrial Estate Cumbernauld Glasgow G68 9HQ United Kingdom	34842	Iib	7
37.	922/016/0404	16G EPIDURAL CUSTOM KIT COLCHESTER GNRL HOSPITAL	Smiths Medical International Ltd. 52 Grayhill Road Westfield Industrial Estate Cumbernauld Glasgow G68 9HQ United Kingdom	34842	Iib	7
38.	922/016/0409	16G EPIDURAL CUSTOM KIT CNTRL MIDDLESEX HOSPITAL	Smiths Medical International Ltd. 52 Grayhill Road Westfield Industrial Estate Cumbernauld Glasgow G68 9HQ United Kingdom	34842	Iib	7
39.	922/016/0411	16G CUSTOM EPIDURAL TRAY GUYS & ST THOMAS NHS TRU	Smiths Medical International Ltd. 52 Grayhill Road Westfield Industrial Estate Cumbernauld Glasgow G68 9HQ United Kingdom	34842	Iib	7
40.	922/016/0442	16G EPIDURAL CUSTOM KIT WHISTON HOSPITAL	Smiths Medical International Ltd. 52 Grayhill Road Westfield Industrial Estate Cumbernauld Glasgow G68 9HQ United Kingdom	34842	Iib	7
41.	922/016/0472	16G EPIDURAL CUSTOM KIT LINCOLN HOSPITAL	Smiths Medical International Ltd. 52 Grayhill Road Westfield Industrial Estate Cumbernauld Glasgow G68 9HQ United Kingdom	34842	Iib	7
42.	922/016/0475	16G EPIDURAL CUSTOM KIT CHRISTIES HOS MANCHESTER	Smiths Medical International Ltd. 52 Grayhill Road Westfield Industrial Estate Cumbernauld Glasgow G68 9HQ United Kingdom	34842	Iib	7

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43.	922/016/0483	16G EPIDURAL CUSTOM KIT, QUEEN ELIZABETH HOSPITAL-KINGS LYNN	Smiths Medical International Ltd. 52 Grayhill Road Westfield Industrial Estate Cumbernauld Glasgow G68 9HQ United Kingdom	34842	Ilb	7
44.	922/016/0509	16G EPIDURAL KIT ROYAL CORNWALL	Smiths Medical International Ltd. 52 Grayhill Road Westfield Industrial Estate Cumbernauld Glasgow G68 9HQ United Kingdom	34842	Ilb	7
45.	922/016/0539	16G EPIDURAL CUSTOM KIT LEWISHAM HOSPITAL	Smiths Medical International Ltd. 52 Grayhill Road Westfield Industrial Estate Cumbernauld Glasgow G68 9HQ United Kingdom	34842	Ilb	7
46.	922/016/0555	16G EPIDURAL CUSTOM KIT FOR BUPA	Smiths Medical International Ltd. 52 Grayhill Road Westfield Industrial Estate Cumbernauld Glasgow G68 9HQ United Kingdom	34842	Ilb	7
47.	922/016/0566	16G EPIDURAL CUSTOM KIT FOR SOUTHPORT AND ORMSKIRK	Smiths Medical International Ltd. 52 Grayhill Road Westfield Industrial Estate Cumbernauld Glasgow G68 9HQ United Kingdom	34842	Ilb	7
48.	922/016/0580	16G CUSTOM EPIDURAL KIT (ROYAL LIVERPOOL)	Smiths Medical International Ltd. 52 Grayhill Road Westfield Industrial Estate Cumbernauld Glasgow G68 9HQ United Kingdom	34842	Ilb	7
49.	922/016/0585	16g EPIDURAL KIT WREXHAM MAELOR NE WALES TRUST	Smiths Medical International Ltd. 52 Grayhill Road Westfield Industrial Estate Cumbernauld Glasgow G68 9HQ United Kingdom	34842	Ilb	7

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50.	922/016/0591	EPIDURAL CUSTOM PACK WHIPPS CROSS	Smiths Medical International Ltd. 52 Grayhill Road Westfield Industrial Estate Cumbernauld Glasgow G68 9HQ United Kingdom	34842	IIB	7
51.	922/016/0592	16G EPIDURAL CUSTOM PACK QUEENS HOSPITAL	Smiths Medical International Ltd. 52 Grayhill Road Westfield Industrial Estate Cumbernauld Glasgow G68 9HQ United Kingdom	34842	IIB	7
52.	922/016/0608	EPIDURAL CUSTOM KIT 16G SOUTHEND HOSP TRUST	Smiths Medical International Ltd. 52 Grayhill Road Westfield Industrial Estate Cumbernauld Glasgow G68 9HQ United Kingdom	34842	IIB	7
53.	922/016/0624	EPIDURAL PROCEDURE KIT, SOUTHMEAD HOSPITAL	Smiths Medical International Ltd. 52 Grayhill Road Westfield Industrial Estate Cumbernauld Glasgow G68 9HQ United Kingdom	34842	IIB	7
54.	922/016/0632	16G CUSTOM EPIDURAL PACK, HYWEL Dda LHB	Smiths Medical International Ltd. 52 Grayhill Road Westfield Industrial Estate Cumbernauld Glasgow G68 9HQ United Kingdom	34842	IIB	7
55.	922/016/0636	16G CUSTOM EPIDURAL KIT UNIVERSITY HOSPITAL BRISTOL	Smiths Medical International Ltd. 52 Grayhill Road Westfield Industrial Estate Cumbernauld Glasgow G68 9HQ United Kingdom	34842	IIB	7

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56.	922/016/0642	16G EPIDURAL VICTORIA HOSPITAL	Smiths Medical International Ltd. 52 Grayhill Road Westfield Industrial Estate Cumbernauld Glasgow G68 9HQ United Kingdom	34842	IIb	7
57.	922/016/0651	16G EPIDURAL PACK FOR PORTLAOIS GENERAL HOSPITAL	Smiths Medical International Ltd. 52 Grayhill Road Westfield Industrial Estate Cumbernauld Glasgow G68 9HQ United Kingdom	34842	IIb	7
58.	922/016/0681	16G EPIDURAL KIT BRISTOL ROYAL INFIRMARY	Smiths Medical International Ltd. 52 Grayhill Road Westfield Industrial Estate Cumbernauld Glasgow G68 9HQ United Kingdom	34842	IIb	7
59.	922/016/0682	16G EPIDURAL PACK VARNAMO	Smiths Medical International Ltd. 52 Grayhill Road Westfield Industrial Estate Cumbernauld Glasgow G68 9HQ United Kingdom	34842	IIb	7
60.	922/016/0685	16G EPIDURAL SET	Smiths Medical International Ltd. 52 Grayhill Road Westfield Industrial Estate Cumbernauld Glasgow G68 9HQ United Kingdom	34842	IIb	7
61.	922/018/0243	18G EPIDURAL CUSTOM KITS FOR BOOTS HEALTHCARE	Smiths Medical International Ltd. 52 Grayhill Road Westfield Industrial Estate Cumbernauld Glasgow G68 9HQ United Kingdom	34842	IIb	7
62.	922/018/0279	18G EPIDURAL CUSTOM KIT FOR TECNICAS MEDICASMAB	Smiths Medical International Ltd. 52 Grayhill Road Westfield Industrial Estate Cumbernauld Glasgow G68 9HQ United Kingdom	34842	IIb	7

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Num	Catalog Number	Product Description	Manufacturing Site	GMDN Code	EU Risk Class	EU Rule
63.	922/018/0291	18G EPIDURAL CUSTOM KIT FOR HARROGATE DIST HOSP	Smiths Medical International Ltd. 52 Grayhill Road Westfield Industrial Estate Cumbernauld Glasgow G68 9HQ United Kingdom	34842	Iib	7
64.	922/018/0309	18G EPIDURAL CUSTOM KIT FOR TECNICAS MAB	Smiths Medical International Ltd. 52 Grayhill Road Westfield Industrial Estate Cumbernauld Glasgow G68 9HQ United Kingdom	34842	Iib	7
65.	922/018/0339	18G EPIDURAL CUSTOM KIT SMITHS MEDICAL SPAIN	Smiths Medical International Ltd. 52 Grayhill Road Westfield Industrial Estate Cumbernauld Glasgow G68 9HQ United Kingdom	34842	Iib	7
66.	922/018/0340	18G EPIDURAL CUSTOM KIT FOR TECNICAS MEDICAS	Smiths Medical International Ltd. 52 Grayhill Road Westfield Industrial Estate Cumbernauld Glasgow G68 9HQ United Kingdom	34842	Iib	7
67.	922/018/0392	18G EPIDURAL CUSTOM KIT NORFOLK & NORWICH NHS TR	Smiths Medical International Ltd. 52 Grayhill Road Westfield Industrial Estate Cumbernauld Glasgow G68 9HQ United Kingdom	34842	Iib	7
68.	922/018/0394	18G EPIDURAL CUSTOM KIT	Smiths Medical International Ltd. 52 Grayhill Road Westfield Industrial Estate Cumbernauld Glasgow G68 9HQ United Kingdom	34842	Iib	7
69.	922/018/0403	18G EPIDURAL CUSTOM KIT ROTUNDA MATERNITY HOSP DUBLIN	Smiths Medical International Ltd. 52 Grayhill Road Westfield Industrial Estate Cumbernauld Glasgow G68 9HQ United Kingdom	34842	Iib	7

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70.	922/018/0455	18G EPIDURAL CUSTOM PACK NATIONAL MATERNITY DUBLI	Smiths Medical International Ltd. 52 Grayhill Road Westfield Industrial Estate Cumbernauld Glasgow G68 9HQ United Kingdom	34842	Iib	7
71.	922/018/0520	18G EPIDURAL CUSTOM KIT MANOR HOSPITAL	Smiths Medical International Ltd. 52 Grayhill Road Westfield Industrial Estate Cumbernauld Glasgow G68 9HQ United Kingdom	34842	Iib	7
72.	922/018/0560	BANDEJA EPIDURAL PERSONALIZADA 18G PARA SMITHS ESPANA	Smiths Medical International Ltd. 52 Grayhill Road Westfield Industrial Estate Cumbernauld Glasgow G68 9HQ United Kingdom	34842	Iib	7
73.	922/018/0613	18G CUSTOM KIT FOR OULU UNIVERSITY, LAPPI CENTRAL AND KOKKOLA HOSP MODEL 3	Smiths Medical International Ltd. 52 Grayhill Road Westfield Industrial Estate Cumbernauld Glasgow G68 9HQ United Kingdom	34842	Iib	7
74.	922/018/0630	18G CUSTOMISED KIT ST. VINCENTS UNIVERSITY HOSPITAL	Smiths Medical International Ltd. 52 Grayhill Road Westfield Industrial Estate Cumbernauld Glasgow G68 9HQ United Kingdom	34842	Iib	7
75.	922/018/0643	OBSTETRIC EPIDURAL KIT PRINCESS ROYAL MATERNITY GLASGOW	Smiths Medical International Ltd. 52 Grayhill Road Westfield Industrial Estate Cumbernauld Glasgow G68 9HQ United Kingdom	34842	Iib	7
76.	922/018/0647	18G EPIDURAL PACK PORTLAOIS GENERAL HOSPITAL	Smiths Medical International Ltd. 52 Grayhill Road Westfield Industrial Estate Cumbernauld Glasgow G68 9HQ United Kingdom	34842	Iib	7

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77.	922/018/0658	18G EPIDURAL SET STERIPOLAR	Smiths Medical International Ltd. 52 Grayhill Road Westfield Industrial Estate Cumbernauld Glasgow G68 9HQ United Kingdom	34842	Iib	7
78.	922/018/0661	18G CUSTOMISED EPIDURAL PACK LIMERICK MATERNITY HOSPITAL	Smiths Medical International Ltd. 52 Grayhill Road Westfield Industrial Estate Cumbernauld Glasgow G68 9HQ United Kingdom	34842	Iib	7
79.	922/018/0686	18g EPIDURAL KIT	Smiths Medical International Ltd. 52 Grayhill Road Westfield Industrial Estate Cumbernauld Glasgow G68 9HQ United Kingdom	34842	Iib	7
80.	923/016/0205	16G EPIDURAL CUSTOM KIT EPSOM & ST HELLIER TRUST	Smiths Medical International Ltd. 52 Grayhill Road Westfield Industrial Estate Cumbernauld Glasgow G68 9HQ United Kingdom	34842	Iib	7
81.	925/016/0179	16G EPIDURAL CUSTOM KIT FOR SMITHS MEDICAL AUSTRALIA	Smiths Medical International Ltd. 52 Grayhill Road Westfield Industrial Estate Cumbernauld Glasgow G68 9HQ United Kingdom	34842	Iib	7
82.	925/018/0179	18G EPIDURAL CUSTOM KIT FOR BOOTS HEALTHCARE	Smiths Medical International Ltd. 52 Grayhill Road Westfield Industrial Estate Cumbernauld Glasgow G68 9HQ United Kingdom	34842	Iib	7
83.	925/018/0221	18G EPIDURAL CUST KIT FOR ASQA	Smiths Medical International Ltd. 52 Grayhill Road Westfield Industrial Estate Cumbernauld Glasgow G68 9HQ United Kingdom	34842	Iib	7

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84.	925/118/0097	18G PAEDIATRIC EPIDURAL TRAY	Smiths Medical International Ltd. 52 Grayhill Road Westfield Industrial Estate Cumbernauld Glasgow G68 9HQ United Kingdom	34842	Iib	7
85.	925/216/0232	16G CUSTOM EPIDURAL KIT OSPEDALE DELL'ANGELO	Smiths Medical International Ltd. 52 Grayhill Road Westfield Industrial Estate Cumbernauld Glasgow G68 9HQ United Kingdom	34842	Iib	7
86.	925/218/0233	18G CUSTOM SET OSPEDALE DELL'ANGELO	Smiths Medical International Ltd. 52 Grayhill Road Westfield Industrial Estate Cumbernauld Glasgow G68 9HQ United Kingdom	34842	Iib	7
87.	925/818/0143	18G EPIDURAL, SEVIT	Smiths Medical International Ltd. 52 Grayhill Road Westfield Industrial Estate Cumbernauld Glasgow G68 9HQ United Kingdom	34842	Iib	7
88.	928/018/0006	18G EPIDURAL CUSTOM KIT FOR TECNICAS MEDICAS MAB	Smiths Medical International Ltd. 52 Grayhill Road Westfield Industrial Estate Cumbernauld Glasgow G68 9HQ United Kingdom	34842	Iib	7
89.	931/016/0027	16G EPIDURAL PACK WILLIAM HARVEY HOSPITAL	Smiths Medical International Ltd. 52 Grayhill Road Westfield Industrial Estate Cumbernauld Glasgow G68 9HQ United Kingdom	34842	Iib	7
90.	931/016/0113	16G EPIDURAL CUSTOM KIT RAIGMORE HOSPITAL	Smiths Medical International Ltd. 52 Grayhill Road Westfield Industrial Estate Cumbernauld Glasgow G68 9HQ United Kingdom	34842	Iib	7

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91.	931/018/0068	18G EPDRL CUST KIT CLINQ LAMBERT-LA GARENNE	Smiths Medical International Ltd. 52 Grayhill Road Westfield Industrial Estate Cumbernauld Glasgow G68 9HQ United Kingdom	34842	Ilb	7
92.	932/000/0098	PREP PACK FOR WYCOMBE GEN HOSP	Smiths Medical International Ltd. 52 Grayhill Road Westfield Industrial Estate Cumbernauld Glasgow G68 9HQ United Kingdom	34842	Ila	6
93.	932/000/0373	CUSTOMISED PREP PACK KOKKOLA HOSPITAL FINLAND	Smiths Medical International Ltd. 52 Grayhill Road Westfield Industrial Estate Cumbernauld Glasgow G68 9HQ United Kingdom	34842	Ila	6
94.	932/016/0016	16G EPIDURAL PK KINGS COLLEGE HOSPITAL	Smiths Medical International Ltd. 52 Grayhill Road Westfield Industrial Estate Cumbernauld Glasgow G68 9HQ United Kingdom	34842	Ilb	7
95.	932/016/0030	16G EPID.NEWHAM GENERAL HOSP.	Smiths Medical International Ltd. 52 Grayhill Road Westfield Industrial Estate Cumbernauld Glasgow G68 9HQ United Kingdom	34842	Ilb	7
96.	932/016/0071	16G EPIDURAL, ROYAL BOLTON HOSP	Smiths Medical International Ltd. 52 Grayhill Road Westfield Industrial Estate Cumbernauld Glasgow G68 9HQ United Kingdom	34842	Ilb	7
97.	932/016/0564	16G EPIDURAL CUSTOM KIT KETTERING GEN HOSP NHS TRUST	Smiths Medical International Ltd. 52 Grayhill Road Westfield Industrial Estate Cumbernauld Glasgow G68 9HQ United Kingdom	34842	Ilb	7

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98.	932/016/0720	16G EPIDURAL SET HOMERTON UNIVERSITY HOSPITAL	Smiths Medical International Ltd. 52 Grayhill Road Westfield Industrial Estate Cumbernauld Glasgow G68 9HQ United Kingdom	34842	I Ib	7
99.	932/018/0016	18G EPIDURAL PACK ULSTER HOSPITAL	Smiths Medical International Ltd. 52 Grayhill Road Westfield Industrial Estate Cumbernauld Glasgow G68 9HQ United Kingdom	34842	I Ib	7
100.	932/018/0090	ULLEVAL SYKEHUS HOSPITAL	Smiths Medical International Ltd. 52 Grayhill Road Westfield Industrial Estate Cumbernauld Glasgow G68 9HQ United Kingdom	34842	I Ib	7
101.	932/018/0102	18G EPIDURAL CUSTOM KIT HOPITAL D'ETTERBEEK IXELLES	Smiths Medical International Ltd. 52 Grayhill Road Westfield Industrial Estate Cumbernauld Glasgow G68 9HQ United Kingdom	34842	I Ib	7
102.	932/018/0160	18G EPIDURAL CUSTOM KIT FOR KOKKOLA HOSPITAL	Smiths Medical International Ltd. 52 Grayhill Road Westfield Industrial Estate Cumbernauld Glasgow G68 9HQ United Kingdom	34842	I Ib	7
103.	932/018/0265	18G EPIDURAL CUSTOM KIT FOR KAS GENTOFTE DENMARK	Smiths Medical International Ltd. 52 Grayhill Road Westfield Industrial Estate Cumbernauld Glasgow G68 9HQ United Kingdom	34842	I Ib	7
104.	932/018/0295	18G CUSTOM EPIDURAL KIT ULSTER HOSP PAIN CLINIC	Smiths Medical International Ltd. 52 Grayhill Road Westfield Industrial Estate Cumbernauld Glasgow G68 9HQ United Kingdom	34842	I Ia	6

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105.	932/018/0457	18G EPIDURAL CUSTOM PACK HVIDOVRE HOSP DENMARK	Smiths Medical International Ltd. 52 Grayhill Road Westfield Industrial Estate Cumbernauld Glasgow G68 9HQ United Kingdom	34842	Ilb	7
106.	932/018/0689	18G CUSTOMEPIDURAL SET THERAPEUTIQUE CHR MOUSCRON	Smiths Medical International Ltd. 52 Grayhill Road Westfield Industrial Estate Cumbernauld Glasgow G68 9HQ United Kingdom	34842	Ila	6
107.	932/018/0708	18G EPIDURAL CUSTOM KIT CROSSHOUSE HOSPITAL	Smiths Medical International Ltd. 52 Grayhill Road Westfield Industrial Estate Cumbernauld Glasgow G68 9HQ United Kingdom	34842	Ilb	7
108.	932/018/0721	18G EPIDURAL KIT FOR KUOPIO	Smiths Medical International Ltd. 52 Grayhill Road Westfield Industrial Estate Cumbernauld Glasgow G68 9HQ United Kingdom	34842	Ilb	7
109.	932/018/0736	18G EPIDURAL PACK ST DIMPNA HOSPITAL	Smiths Medical International Ltd. 52 Grayhill Road Westfield Industrial Estate Cumbernauld Glasgow G68 9HQ United Kingdom	34842	Ila	6
110.	934/016/0002	16G EPIDURAL KIT NOTTINGHAM UNIVERSITY HOSPITALS NHS TRUST	Smiths Medical International Ltd. 52 Grayhill Road Westfield Industrial Estate Cumbernauld Glasgow G68 9HQ United Kingdom	34842	Ilb	7
111.	936/016/0092	16G EPIDURAL CUSTOM KIT FOR MACCLESFIELD DISTRICT GEN HOSP	Smiths Medical International Ltd. 52 Grayhill Road Westfield Industrial Estate Cumbernauld Glasgow G68 9HQ United Kingdom	34842	Ilb	7

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Num	Catalog Number	Product Description	Manufacturing Site	GMDN Code	EU Risk Class	EU Rule
112.	936/016/0105	16G EPIDURAL CUSTOM KIT FOR TAYSIDE NHS TRUST	Smiths Medical International Ltd. 52 Grayhill Road Westfield Industrial Estate Cumbernauld Glasgow G68 9HQ United Kingdom	34842	Iib	7
113.	936/016/0119	16G EPIDURAL CUSTOM KIT FOR CH DE ST JUNIEN	Smiths Medical International Ltd. 52 Grayhill Road Westfield Industrial Estate Cumbernauld Glasgow G68 9HQ United Kingdom	34842	Iib	7
114.	936/018/0001	18G EPIDURAL, MATERNITE PINARD	Smiths Medical International Ltd. 52 Grayhill Road Westfield Industrial Estate Cumbernauld Glasgow G68 9HQ United Kingdom	34842	Iib	7
115.	936/018/0009	18G EPID.CLINIQUE COURLANCY REIMS	Smiths Medical International Ltd. 52 Grayhill Road Westfield Industrial Estate Cumbernauld Glasgow G68 9HQ United Kingdom	34842	Iib	7
116.	936/018/0017	HOPITAL MANCHESTER-CHARLEVILLEMEZIERES	Smiths Medical International Ltd. 52 Grayhill Road Westfield Industrial Estate Cumbernauld Glasgow G68 9HQ United Kingdom	34842	Iib	7
117.	936/018/0086	18G EPIDURAL CUSTOM KIT	Smiths Medical International Ltd. 52 Grayhill Road Westfield Industrial Estate Cumbernauld Glasgow G68 9HQ United Kingdom	34842	Iib	7
118.	936/018/0106	18G EPIDURAL CUSTOM KIT FOR TAYSIDE NHS TRUST	Smiths Medical International Ltd. 52 Grayhill Road Westfield Industrial Estate Cumbernauld Glasgow G68 9HQ United Kingdom	34842	Iib	7

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Num	Catalog Number	Product Description	Manufacturing Site	GMDN Code	EU Risk Class	EU Rule
119.	936/018/0190	18G EPIDURAL CUSTOM KIT CHU POITERS	Smiths Medical International Ltd. 52 Grayhill Road Westfield Industrial Estate Cumbernauld Glasgow G68 9HQ United Kingdom	34842	IIb	7
120.	936/018/0234	18G EPIDURAL SET CLINIQUE SAINT-PAUL MARTINIQUE	Smiths Medical International Ltd. 52 Grayhill Road Westfield Industrial Estate Cumbernauld Glasgow G68 9HQ United Kingdom	34842	IIb	7
121.	937/016/0025	16G EPIDURAL CUSTOM KIT FOR ESKILSTUNA	Smiths Medical International Ltd. 52 Grayhill Road Westfield Industrial Estate Cumbernauld Glasgow G68 9HQ United Kingdom	34842	IIb	7
122.	937/016/0056	NORTHAMPTON GENERAL HOSPITAL 16G CUSTOM EPIDURAL PACK	Smiths Medical International Ltd. 52 Grayhill Road Westfield Industrial Estate Cumbernauld Glasgow G68 9HQ United Kingdom	34842	IIb	7
123.	937/016/0097	16G EPIDURAL PACK FOR BLACKPOOL VICTORIA	Smiths Medical International Ltd. 52 Grayhill Road Westfield Industrial Estate Cumbernauld Glasgow G68 9HQ United Kingdom	34842	IIb	7
124.	937/016/0099	16G EPIDURAL PACK NYKOPING LASARETT	Smiths Medical International Ltd. 52 Grayhill Road Westfield Industrial Estate Cumbernauld Glasgow G68 9HQ United Kingdom	34842	IIb	7
125.	937/018/0001	18G EPIDURAL CUSTOM KIT POLYCLINIQUE DE L'ATLANTIQUE	Smiths Medical International Ltd. 52 Grayhill Road Westfield Industrial Estate Cumbernauld Glasgow G68 9HQ United Kingdom	34842	IIb	7

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Num	Catalog Number	Product Description	Manufacturing Site	GMDN Code	EU Risk Class	EU Rule
126.	937/018/0019	18G EPIDURAL CUSTOM KIT UPPSALA SJUKHI KVINNOKLINIKM	Smiths Medical International Ltd. 52 Grayhill Road Westfield Industrial Estate Cumbernauld Glasgow G68 9HQ United Kingdom	34842	Ilb	7
127.	937/018/0027	18G EPIDURAL CUSTOM KIT-WESTMA	Smiths Medical International Ltd. 52 Grayhill Road Westfield Industrial Estate Cumbernauld Glasgow G68 9HQ United Kingdom	34842	Ilb	7
128.	937/018/0083	18G CUSTOM EPIDURAL SET FOR CHR DE MOUSCRON	Smiths Medical International Ltd. 52 Grayhill Road Westfield Industrial Estate Cumbernauld Glasgow G68 9HQ United Kingdom	34842	Ilb	7
129.	937/018/0091	18G EPIDURAL CUSTOM KIT FOR CAPIO ST GORAN	Smiths Medical International Ltd. 52 Grayhill Road Westfield Industrial Estate Cumbernauld Glasgow G68 9HQ United Kingdom	34842	Ilb	7
130.	937/018/0095	NORRLANDSSETET 18G EPIDURAL	Smiths Medical International Ltd. 52 Grayhill Road Westfield Industrial Estate Cumbernauld Glasgow G68 9HQ United Kingdom	34842	Ilb	7
131.	EPICC0034	EPIDURALSET SLL, 18G	Smiths Medical International Ltd. 52 Grayhill Road Westfield Industrial Estate Cumbernauld Glasgow G68 9HQ United Kingdom	34842	Ilb	7
132.	100/395/560	TUOHY NEEDLE 16G 110MM	Smiths Medical International Ltd. 52 Grayhill Road Westfield Industrial Estate Cumbernauld Glasgow G68 9HQ United Kingdom	58293	Ila	6

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Num	Catalog Number	Product Description	Manufacturing Site	GMDN Code	EU Risk Class	EU Rule
133.	100/395/580	TUOHY NEEDLE 18G 110MM	Smiths Medical International Ltd. 52 Grayhill Road Westfield Industrial Estate Cumbernauld Glasgow G68 9HQ United Kingdom	58293	Ila	6
134.	9EPD-113000	EPIDURAL-DURA FLEX KATHETER SET 16G	Smiths Medical Deutschland GmbH Werdauer Strasse 51 D-08427 Fraureuth, Germany	34842	IIb	7
135.	9EPD-113001	EPIDURAL-SET, 18G	Smiths Medical Deutschland GmbH Werdauer Strasse 51 D-08427 Fraureuth, Germany	34842	IIb	7
136.	9EPD-113002	EPIDURAL-SET 18G	Smiths Medical Deutschland GmbH Werdauer Strasse 51 D-08427 Fraureuth, Germany	34842	IIb	7
137.	9EPD-122002	EPIDURAL-SET, 18G	Smiths Medical Deutschland GmbH Werdauer Strasse 51 D-08427 Fraureuth, Germany	34842	IIb	7
138.	9EPD-241001	EPIDURAL SET 16G DURA FLEX KATHETER	Smiths Medical Deutschland GmbH Werdauer Strasse 51 D-08427 Fraureuth, Germany	34842	IIb	7
139.	9EPD-395180	TUOHY-NADEL 18 G X 80 MM MIT GRIFFPLATTE	Smiths Medical Deutschland GmbH Werdauer Strasse 51 D-08427 Fraureuth, Germany	34842	Ila	6
140.	9EPD-402103	Epiduralset 18G AKH Linz	Smiths Medical Deutschland GmbH Werdauer Strasse 51 D-08427 Fraureuth, Germany	34842	IIb	7
141.	9EPD-602002	EPIDURAL-SET 18G	Smiths Medical Deutschland GmbH Werdauer Strasse 51 D-08427 Fraureuth, Germany	34842	IIb	7
142.	9EPD-735001	REG. ZUBEHÖR-SET LKH-OBERPULLENDORF	Smiths Medical Deutschland GmbH Werdauer Strasse 51 D-08427 Fraureuth, Germany	35246	Ila	6
143.	9EPD-740001	EPIDURAL-SET 18G OBERWART	Smiths Medical Deutschland GmbH Werdauer Strasse 51 D-08427 Fraureuth, Germany	34842	IIb	7
144.	9EPD-856141	DURA FLEX 17G & DURA FLEX 19G	Smiths Medical Deutschland GmbH Werdauer Strasse 51 D-08427 Fraureuth, Germany	34842	IIb	7

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Num	Catalog Number	Product Description	Manufacturing Site	GMDN Code	EU Risk Class	EU Rule
145.	EPIFC00202	DURAFLEX MAXI EPIDURAL SET	Smiths Medical Deutschland GmbH Werdauer Strasse 51 D-08427 Fraureuth, Germany	34842	Ilb	7
146.	EPIFC00602	SINGLE SHOT EPIDURAL 18G GLAS	Smiths Medical Deutschland GmbH Werdauer Strasse 51 D-08427 Fraureuth, Germany	34842	Ila	7
147.	EPIFC00901	FEMORALIS SET LILIENFELD	Smiths Medical Deutschland GmbH Werdauer Strasse 51 D-08427 Fraureuth, Germany	34842	Ila	6
148.	EPIFC01201	EPIDURAL SET (921/016/0177) LKH GRAZ	Smiths Medical Deutschland GmbH Werdauer Strasse 51 D-08427 Fraureuth, Germany	34842	Ilb	7
149.	MAX161	EPIDURAL MAXIPACK 16G	Smiths Medical Deutschland GmbH Werdauer Strasse 51 D-08427 Fraureuth, Germany	34842	Ilb	7
150.	MAX181	EPIDURAL MAXIPACK 18G	Smiths Medical Deutschland GmbH Werdauer Strasse 51 D-08427 Fraureuth, Germany	34842	Ilb	7
151.	MAXL161	EPIDURAL MAXIPACK 16G LOR	Smiths Medical Deutschland GmbH Werdauer Strasse 51 D-08427 Fraureuth, Germany	34842	Ilb	7
152.	MAXL181	EPIDURAL MAXIPACK 18G LOR	Smiths Medical Deutschland GmbH Werdauer Strasse 51 D-08427 Fraureuth, Germany	34842	Ilb	7
153.	SXP566702	BASIS-SET REGIONALANÄSTHESIE WIEN, RUDOLFSTIFTUNG KH	Smiths Medical Deutschland GmbH Werdauer Strasse 51 D-08427 Fraureuth, Germany	34842	Ila	6
154.	18/944/C3N	CATHETER, CLOSED END, 3 LATERAL EYES, WITHOUT STYLET WITH LOCKIT PLUS	Smiths Medical ASD, Inc 10 Bowman Drive Keene, NH 03431 USA	46383	Ilb	7
155.	18/944/C3S	CATHETER, CLOSED END, 3 LATERAL EYES, WITH STYLET WITH LOCKIT PLUS	Smiths Medical ASD, Inc 10 Bowman Drive Keene, NH 03431 USA	46383	Ilb	7
156.	4909E	EPIFUSE EPIDURAL CATHETER CONNECTOR	Smiths Medical ASD, Inc 10 Bowman Drive Keene, NH 03431 USA	63606	Ila	2

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Num	Catalog Number	Product Description	Manufacturing Site	GMDN Code	EU Risk Class	EU Rule
157.	E621	17G EPIDURAL MAXIPACK GLASS LORD, CLOSED CATH, FILT	Smiths Medical ASD, Inc 10 Bowman Drive Keene, NH 03431 USA	34842	Ilb	7
158.	E622	17G EPIDURAL MAXIPACK WITH GLOR OEC	Smiths Medical ASD, Inc 10 Bowman Drive Keene, NH 03431 USA	34842	Ilb	7
159.	E623	17G EPIDURAL MINIPACK W/O LORDOPEN END CATHETER	Smiths Medical ASD, Inc 10 Bowman Drive Keene, NH 03431 USA	34842	Ilb	7
160.	G745	18G EPIDURAL MAXIPACK WITH GLOR OEC	Smiths Medical ASD, Inc 10 Bowman Drive Keene, NH 03431 USA	34842	Ilb	7
161.	G747	17G EPIDURAL MINIPACK OEC P LOR	Smiths Medical ASD, Inc 10 Bowman Drive Keene, NH 03431 USA	34842	Ilb	7
162.	4893CS	CORRECTINJECT 3ML LOCK SYRINGE KIT	Smiths Medical ASD, Inc 10 Bowman Drive Keene, NH 03431 USA	35904	Ila	3
163.	G748	18G EPIDURAL MINIPACK PLASTIC LORD, CLOSED END CATH.	Smiths Medical ASD, Inc 10 Bowman Drive Keene, NH 03431 USA	34842	Ilb	7
164.	G749	18G EPIDURAL MINIPACK PLASTIC LORD, OPEN END CATH.	Smiths Medical ASD, Inc 10 Bowman Drive Keene, NH 03431 USA	34842	Ilb	7
165.	G895	18G EPIDURAL MAXIPACK GLASS LOR CEC	Smiths Medical ASD, Inc 10 Bowman Drive Keene, NH 03431 USA	34842	Ilb	7
166.	G998	17G EPIDURAL MINIPACK PLASTIC LORD, CLOSED END CATH.	Smiths Medical ASD, Inc 10 Bowman Drive Keene, NH 03431 USA	34842	Ilb	7
167.	J600/61	18G EPIDURAL MINIPACK PLASTIC LORD, CLOSED END CATH.	Smiths Medical ASD, Inc 10 Bowman Drive Keene, NH 03431 USA	34842	Ilb	7
168.	J601/61	18G EPIDURAL MAXIPACK CUSTOM	Smiths Medical ASD, Inc 10 Bowman Drive Keene, NH 03431 USA	34842	Ilb	7

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Num	Catalog Number	Product Description	Manufacturing Site	GMDN Code	EU Risk Class	EU Rule
169.	J602/61	18G EPIDURAL MAXIPACK CUSTOM SPAIN	Smiths Medical ASD, Inc 10 Bowman Drive Keene, NH 03431 USA	34842	Ilb	7
170.	J605/61	17G EPIDURAL MAXIPACK CUSTOM SPAIN	Smiths Medical ASD, Inc 10 Bowman Drive Keene, NH 03431 USA	34842	Ilb	7
171.	J637/61	17G EPIDURAL MAXIPACK CUSTOM SPAIN	Smiths Medical ASD, Inc. 10 Bowman Dr. Keene, NH 03431 USA	34842	Ilb	7
172.	L794	18G EPIDURAL MAXIPACK PLASTIC LORD CLOSED END CATH.	Smiths Medical ASD, Inc 10 Bowman Drive Keene, NH 03431 USA	34842	Ilb	7
173.	100/395/160	TUOHY NEEDLE 16G 80MM	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	58293	Ila	6
174.	100/395/180	TUOHY NEEDLE 18G 80MM	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	58293	Ila	6
175.	SPIFC00601	SPINALSET LILIENFELD	Smiths Medical Deutschland GmbH Werdauer Strasse 51 D-08427 Fraureuth, Germany	33961	Ila	6
176.	L728-61	18G TOUHY NEEDLE SINGLE PACKED	Smiths Medical ASD, Inc 10 Bowman Drive Keene, NH 03431 USA	58293	Ila	6

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Appendix 2: Revision History

Revision Number	Summary of Changes / Additions	Created / Revised by	Date
005	Updated to latest DoC template updated ec certificate information	Breanna Fautsch	30-NOV-2016
005-2	Updated the EC Cert Info	Manasa Boppana	16-MAY-2017
006	Change document number format from SXXX to DoCXXX to load documents into Agile. No updates made to content of this document with the exception of the document number from S1177 to DoC-127 and revision from 005 to 006 and added STED # to header for traceability to STED. Removed Notified Body address for consistency across all DoCs. The purpose of this revision update was in response to a Notified Body Transfer. The changes made to this DoC include: Notified Body name from Intertek to BSI, update the certification number from 091-01 B CE to CE 660824, update revision from 006 to 007. There were three parts removed (925/216/0163, 925/216/0164 and 925/218/0163) because they have no EU risk classification and are for the Japanese market. There were two other parts (925/016/0179 and 925/018/0179) were removed because they have no EU risk classification, but they are for the Australian market. Removed table of Annex V/Class Is products, as they should be in a separate DoC (100/399/216, 100/399/218, 932/000/0563, 934/000/0004, F031-61), these products moved to DoC-175. Removed parts with Agile item status inactive, service and obsolete. No other updates were made. Removed "for Class IIa and IIb" under Conformity Assessment section.	Brent Pearson	15-SEP-2017
007	Updated DoC to the latest Template in Agile. Added new SKU's from the Portex Pain NRFIT™ and EchoGlo™ products in the DoC as these are new products with CE mark.	Mitchell Madsen	18-OCT-2017
108	The purpose of this revision is to remove the Portex Pain NRFit™ and EchoGlo™ products which currently do not have CE marking to be sold into the EU. Additionally the revision of the DoC went from Rev. 007 to Rev. 108, according to	Dominique Neisz	03-OCT-2018

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Revision Number	Summary of Changes / Additions	Created / Revised by	Date
	DVSOP2005 production document revisions went from a 0## format to a 1## format. No revisions were skipped between revision 007 and 108. Updated Authorized Signatory to Sunita Teekasingh.		
109	This revision was made to align with the STED and ERC so that all three documents are at the same revision which is revision 109. No other technical content review or updates were performed during this revision update.	Mitchell Madsen	05-OCT-2018
110	Changed the Manufacturing Site for 100/395/560 and 100/395/580 from FRA to CMB due to Customer Inquiry #17377 – the inquiry noted a discrepancy in Manufacturing Site between DoC-127 and the SKUs' labels. Agile and the labels confirmed the Manufacturing Site to be CMB. Changed Manufacturing Site from FRA to MKEE for 18/944/AN, 18/944/AS, 18/944/C3N, 18/944/C3S, 4909E, E621, E622, E623, G745, G747, 4893CS to match Agile. Lou Ruff (Quality Assurance Supervisor from Keene) confirmed the SKUs are manufactured in Keene. Removed 922/016/0333, 937/018/0054, 9EPD-116004, 9EPD-235621, 9EPD-481491, 9EPD-506782, 9EPD-528001, 9EPD-531051, 9EPD-633001, 9EPD-835122 as they are obsolete in Agile. Revised FRA and TIJ addresses to match EC Certificate CE 660824. Unmerged cells for easier reading and editing. Adding Product Family/Product Line Agile attribute as it is currently blank.	Alicia Wilson	13-FEB-2019
111	-Changed the legal manufacturer from MKEE to MMSP as per FM-DVSOP8005-05. -Changed the EU Representative from the Ashford, UK facility to the Hranice, Czech Republic facility. An EU Representative is needed if a product is commercially distributed in the EU and not manufactured in the EU. Since Ashford will no longer be part of the EU, due to Brexit, the EU Representative was changed from the Ashford facility to the Hranice facility. -Changed the Notified Body from BSI UK (0086) to BSI NL (2797) as BSI is migrating issued certificates from the UK to	Mitchell Madsen	14-OCT-2019

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	the Netherlands due to Brexit. Changed the EC Certificate from CE 660826 to CE 669121 due to the Legal Manufacturer change. -Changed the Product Descriptions for the Catalog Numbers in Appendix 1 to match their Agile Descriptions -Updated the Cumbernauld address in the Manufacturing Site column in Appendix 1 to match the EC Certificate, CE 669121. -Updated the Fraureuth address in the Manufacturing Site column in Appendix 1 to match the EC Certificate, CE 669121. -Updated the Tijuana address in the Manufacturing Site column in Appendix 1 to match the EC Certificate, CE 669121. -Removed the following Catalog Numbers from Appendix 1 due to being Inactive and Post Phase Out lifecycle phase: 937/000/0111, 9EPD-116002, 9EPD-391118, 4894CS, 4895CS, 4896CS, J606/61, 922/018/0244, 925/018/0200, 925/018/0214, 932/000/0118, 932/016/0183, 932/018/0005, 932/018/0477, 932/018/0478, 936/016/0153, 936/016/0154, 937/018/0101, EPIFC00401, EPIFC01401, 18/944/AN, 18/944/AS, G997-61, J604/61, 100/382/019, 129/391/118, 915/016/0022, 915/216/0023, 915/218/0023 -Changed the GMDN Code for 18/944/C3N and 18/944/C3S from 35795 to 46383 as the GMDN Agency obsoleted 35795 and 46383 is the best fit replacement code. Changed the GMDN Code for G747 and G748 from 35795 to 34842 as the GMDN Agency obsoleted 35795 and 34842 is the best fit replacement code. Changed the GMDN Code for 9EPD-735001 from 34842 to 35246 as a more appropriate term assignment. Changed the GMDN Code for 4909E from 46115 to 63606 due to GMDN Code obsolescence.		
112	Added SKUs EPIFC01201, SPIFC00601 and L728-61 in order to commercially distribute in the EU. SPIFC00601 was originally identified as a class III device, however upon review	Alicia Wilson	04-DEC-2019

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	it was determined to be IIa as it does not contain any spinal needles and it only used as a prep kit for spinal procedures to apply a local anesthetic (not included).		