

	Declaration of Conformity	DoC-115 Revision Number: 104 Effective Date: 10-AUG-2018
	S1144: Port-A-Cath® Accessories	

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

EU Representative: Smiths Medical International Limited
1500 Eureka Park Lower Pemberton
Ashford Kent TN25 4BF UK

Product Tradename(s): GRIPPER® needle, GRIPPER PLUS® needle and needle protection device, GRIPPER PLUS® POWER P.A.C. needle and needle protection device (capacity for use with power injection), GRIPPER MICRO® needle and needle protection device, and PORT-A-CATH® Needles

Product Scope: Sterile Needles and Introducer for Implantable Access

Conformity Assessment Route: Annex II (excluding Section 4)

Notified Body: BSI Healthcare
Medical Devices Certification
Notified Body #0086

EC Certificate Number: CE 669121

Start of CE-Marking: 17 May 2010

We hereby declare that the products listed in Appendix 1 conform with the relevant provisions of Directive 93/42/EEC of June 14, 1993 as transposed into UK law by Statutory Instrument S.I. 2008 No. 2936 and as amended by Directive 2007/47/EC of the European Parliament and of the Council of September 5, 2007 concerning medical devices as transposed into national regulations and by subsequent Directives, laws, and other national regulations. We are hereby exclusively responsible for the contents found on this declaration of conformity. All supporting documentation is retained under the premise of the Manufacturer.

Authorized Signatory:

Signature:



Date: 10-Aug-2018

Name: Gary Barrett

Title: VP, Quality Systems

Location of Signatory: Minneapolis, MN, USA

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Appendix 1: Product List

Num	Catalog Number	Product Description	Manufacturing Site	UMDNS (if applicable)	GMDN Code	EU Risk Class	EU Rule
1.	21-2320-24	Peel-Away Introducer Set 6Fr	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4 Parque Industrial Internacional Tijuana, Baja California 22425 Mexico	N/A	17180	IIa	7
2.	21-2340-24	Peel-Away Introducer Set 9Fr					
3.	21-2386-24	Peel-Away Introducer Set 11Fr					
4.	21-2470-24	Peel-Away Introducer Set 8.5F					
5.	21-2471-24	Peel-Away Introducer Set 7Fr					
6.	21-2472-24	Peel-Away Introducer Set 10F					
7.	21-2476-24	Valved Peel-Away Introducer Set 6Fr					
8.	21-2477-24	Valved Peel-Away Introducer Set 7Fr					
9.	21-2478-24	Valved Peel-Away Introducer Set 8.5Fr					
10.	21-2479-24	Valved Peel-Away Introducer Set 9Fr					
11.	21-2480-24	Valved Peel-Away Introducer Set 10Fr					
12.	21-2481-24	Valved Peel-Away Introducer Set 11Fr					
13.	21-2714-24	GRIPPER® Needles: NDL, GRIPPER, 0.7 mm (22 G) x 25mm (1 in.)					
14.	21-2715-24	GRIPPER® Needles: NDL, GRIPPER, 0.7 mm (22 G) x 32mm (1 1/4 in.)					
15.	21-2717-24	GRIPPER® Needles: NDL, GRIPPER, 0.9 mm (20 G) x 25mm (1 in.)					
16.	21-2718-24	GRIPPER® Needles: NDL, GRIPPER, 0.9 mm (20 G) x 32mm (1 1/4 in.)					
17.	21-2720-24	GRIPPER® Needles: NDL, GRIPPER, 1.1 mm (19 G) x 25mm (1 in.)					
18.	21-2721-24	GRIPPER® Needles: NDL, GRIPPER, 1.1 mm (19 G) x 32mm (1 1/4 in.)					
19.	21-2733-24	GRIPPER® Needles: NDL, GRIPPER, 0.7 mm (22 G) x 19mm (3/4 in.)					
20.	21-2734-24	GRIPPER® Needles: NDL, GRIPPER, 0.9 mm (20 G) x 19mm (3/4 in.)					

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21.	21-2735-24	GRIPPER® Needles: NDL, GRIPPER, 1.1 mm (19 G) x 19mm (3/4 in.)	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4 Parque Industrial Internacional Tijuana, Baja California 22425 Mexico	N/A	17180	IIa	7
22.	21-2736-24	GRIPPER® Needles: NDL, GRIPPER, 0.9 mm (20 G) x 16mm (5/8 in.)					
23.	21-2737-24	GRIPPER® Needles: NDL, GRIPPER, 0.7 mm (22 G) x 16mm (5/8 in.)					
24.	21-2760-24	GRIPPER® Needles: NDL, GRIPPER PLUS, 0.7 mm (22 G) x 25mm (1 in.)					
25.	21-2761-24	GRIPPER® Needles: NDL, GRIPPER PLUS, 0.7 mm (22 G) x 32mm (1 1/4 in.)					
26.	21-2762-24	GRIPPER® Needles: NDL, GRIPPER PLUS, 0.9 mm (20 G) x 25mm (1 in.)					
27.	21-2763-24	GRIPPER® Needles: NDL, GRIPPER PLUS, 0.9 mm (20 G) x 32mm (1 1/4in.)					
28.	21-2764-24	GRIPPER® Needles: NDL, GRIPPER PLUS, 1.1 mm (19 G) x 25mm (1 in.)					
29.	21-2765-24	GRIPPER® Needles: NDL, GRIPPER PLUS, 1.1 mm (19 G) x 32mm (1 1/4 in.)					
30.	21-2766-24	GRIPPER® Needles: NDL, GRIPPER PLUS, 0.7 mm (22 G) x 19mm (3/4 in.)					
31.	21-2767-24	GRIPPER® Needles: NDL, GRIPPER PLUS, 0.9 mm (20 G) x 19mm (3/4 in.)					
32.	21-2768-24	GRIPPER® Needles: NDL, GRIPPER PLUS, 1.1 mm (19 G) x 19mm (3/4 in.)					
33.	21-2769-24	GRIPPER® Needles: NDL, GRIPPER PLUS, 0.9 mm (20 G) x 16mm (5/8 in.)					
34.	21-2770-24	GRIPPER® Needles: NDL, GRIPPER PLUS, 0.7 mm (22 G) x 16mm (5/8 in.)					
35.	21-2860-24	GRIPPER® Needles: NDL, GRIPPER PLUS, 0.7 mm (22 G) x 16mm (5/8 in.), Y-SITE					
36.	21-2861-24	GRIPPER® Needles: NDL, GRIPPER PLUS, 0.7 mm (22 G) x 19mm (3/4 in.), Y-SITE					



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37.	21-2862-24	GRIPPER® Needles: NDL, GRIPPER PLUS, 0.7 mm (22 G) x 25mm (1 in.), Y-SITE	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4 Parque Industrial Internacional Tijuana, Baja California 22425 Mexico	N/A	17180	IIa	7
38.	21-2863-24	GRIPPER® Needles: NDL, GRIPPER PLUS, 0.7 mm (22 G) x 32mm (1 1/4 in.), Y-SITE					
39.	21-2864-24	GRIPPER® Needles: NDL, GRIPPER PLUS, 0.9 mm (20 G) x 16mm (5/8 in.), Y-SITE					
40.	21-2865-24	GRIPPER® Needles: NDL, GRIPPER PLUS, 0.9 mm (20 G) x 19mm (3/4 in.), Y-SITE					
41.	21-2866-24	GRIPPER® Needles: NDL, GRIPPER PLUS, 0.9 mm (20 G) x 25mm (1 in.), Y-SITE					
42.	21-2867-24	GRIPPER® Needles: NDL, GRIPPER PLUS, 0.9 mm (20 G) x 32mm (1 1/4 in.), Y-SITE					
43.	21-2868-24	GRIPPER® Needles: NDL, GRIPPER PLUS, 1.1 mm (19 G) x 19mm (3/4 in.), Y-SITE					
44.	21-2869-24	GRIPPER® Needles: NDL, GRIPPER PLUS, 1.1 mm (19 G) x 25mm (1 in.), Y-SITE					
45.	21-2870-24	GRIPPER® Needles: NDL, GRIPPER PLUS, 1.1 mm (19 G) x 32mm (1 1/4 in.), Y-SITE					
46.	21-2938-24	GRIPPER® Needles: NDL, GRIPPER, 0.7 mm (22 G) x 16mm (5/8 in.), Y-SITE					
47.	21-2939-24	GRIPPER® Needles: NDL, GRIPPER, 0.7 mm (22 G) x 19mm (3/4 in.), Y-SITE					
48.	21-2940-24	GRIPPER® Needles: NDL, GRIPPER, 0.7 mm (22 G) x 25mm (1 in.), Y-SITE					
49.	21-2941-24	GRIPPER® Needles: NDL, GRIPPER, 0.7 mm (22 G) x 32mm (1 1/4 in.), Y-SITE					
50.	21-2946-24	GRIPPER® Needles: NDL, GRIPPER, 0.9 mm (20 G) x 16mm (5/8 in.), Y-SITE					

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51.	21-2947-24	GRIPPER® Needles: NDL, GRIPPER, 0.9 mm (20 G) x 19mm (3/4 in.), Y-SITE	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4 Parque Industrial Internacional Tijuana, Baja California 22425 Mexico	N/A	17180	IIa	7
52.	21-2948-24	GRIPPER® Needles: NDL, GRIPPER, 0.9 mm (20 G) x 25mm (1 in.), Y-SITE					
53.	21-2949-24	GRIPPER® Needles: NDL, GRIPPER, 0.9 mm (20 G) x 32mm (1 1/4 in.), Y-SITE					
54.	21-2955-24	GRIPPER® Needles: NDL, GRIPPER, 1.1 mm (19 G) x 19mm (3/4 in.), Y-SITE					
55.	21-2956-24	GRIPPER® Huber Needles: 1.1 mm (19 G) x 25mm (1 in.), Extension Set with Y-SITE					
56.	21-2957-24	GRIPPER® Huber Needles, 1.1 mm (19 G) x 32mm (1 1/4 in.) Extension Set with Y-SITE					
57.	21-2960-24	GRIPPER® Plus Safety Huber Needles 0.7 mm (22 G) x 16mm (5/8 in.), NEEDLELESS Y-SITE					
58.	21-2961-24	GRIPPER® Plus Safety Huber Needles, 0.7 mm (22 G) x 19mm (3/4 in.), NEEDLELESS Y-SITE					
59.	21-2962-24	GRIPPER® Plus Safety Huber Needles, 0.7 mm (22 G) x 25mm (1 in.), NEEDLELESS Y-SITE					
60.	21-2963-24	GRIPPER® Plus Safety Huber Needles, 0.7 mm (22 G) x 32mm (1 1/4 in.), NEEDLELESS Y-SITE					
61.	21-2964-24	GRIPPER® Plus Safety Huber Needles, 0.9 mm (20 G) x 16mm (5/8 in.), NEEDLELESS Y-SITE					
62.	21-2965-24	GRIPPER® Plus Safety Huber Needles, 0.9 mm (20 G) x 19mm (3/4 in.), NEEDLELESS Y-SITE					
63.	21-2966-24	GRIPPER® Plus Safety Huber Needles, 0.9 mm (20 G) x 25mm (1 in.), NEEDLELESS Y-SITE					

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Num	Catalog Number	Product Description	Manufacturing Site	UMDNS (if applicable)	GMDN Code	EU Risk Class	EU Rule
64.	21-2967-24	GRIPPER® Plus Safety Huber Needles 0.9 mm (20 G) x 32mm (1 1/4in.), NEEDLELESS Y-SITE	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4 Parque Industrial Internacional Tijuana, Baja California 22425 Mexico	N/A	17180	IIa	7
65.	21-2968-24	GRIPPER® Plus Safety Huber Needles, 1.1 mm (19 G) x 19mm (3/4 in.), NEEDLELESS Y-SITE					
66.	21-2969-24	GRIPPER® Plus Safety Huber Needles US, 1.1 mm (19 G) x 25mm (1 in.), NEEDLELESS Y-SITE					
67.	21-2970-24	GRIPPER® Plus Safety Huber Needles, 1.1 mm (19 G) x 32mm (1 1/4 in.), NEEDLELESS Y-SITE					
68.	21-3362-24	GRIPPER PLUS® Safety Huber Needles 0.9mm (20 G) x 25mm (1 in.) 20 cm (8 in.) Extension Set without Y-Site					
69.	21-3363-24	GRIPPER PLUS® Safety Huber Needles 0.9mm (20 G) x 32mm (1 1/4 in.) 20 cm (8 in.) Extension Set without Y-Site					
70.	21-3364-24	GRIPPER PLUS® Safety Huber Needles, 1.1mm (19 G) x 25mm (1 in.) 20 cm (8 in.) Extension Set without Y-Site					
71.	21-3365-24	GRIPPER PLUS® Safety Huber Needles 1.1mm (19 G) x 32mm (1 1/4 in.) 20 cm (8 in.) Extension Set without Y-Site					
72.	21-3367-24	GRIPPER PLUS® Safety Huber Needles 0.9mm (20 G) x 19mm (3/4 in.) 20 cm (8 in.) Extension Set without Y-Site					
73.	21-3368-24	GRIPPER PLUS® Safety Huber Needles 1.1mm (19 G) x 19mm (3/4 in.) 20 cm (8 in.) Extension Set without Injection Site					



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74.	21-3369-24	GRIPPER PLUS® Safety Huber Needles, 0.9mm (20 G) x 16mm (5/8 in.) 20 cm (8 in.) Extension Set without Injection Site	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4 Parque Industrial Internacional Tijuana, Baja California 22425 Mexico	N/A	17180	IIa	7
75.	21-3464-24	GRIPPER PLUS® Safety Huber Needles, 0.9mm (20 G) x 16mm (5/8 in.) 20 cm (8 in.) Extension Set with luer activated needleless injection Y-site					
76.	21-3465-24	GRIPPER PLUS® Safety Huber Needles 0.9mm (20 G) x 19mm (3/4 in.) 20 cm (8 in.) Extension Set with luer activated needleless injection Y-site					
77.	21-3466-24	GRIPPER PLUS® Safety Huber Needles, 0.9mm (20 G) x 25mm (1 in.) 20 cm (8 in.) Extension Set with luer activated needleless injection Y-site					
78.	21-3467-24	GRIPPER PLUS® POWER P.A.C. Needles: NDL, GRIPPER PLUS, PWR INJECTABLE, 0.9mm (20 G) x 32mm (1 1/4 in.) 20 cm (8 in.) Extension Set with luer activated needleless injection Y-site					
79.	21-3468-24	GRIPPER PLUS® POWER P.A.C. Needles: NDL, GRIPPER PLUS, PWR INJECTABLE, 1.1mm (19 G) x 19mm (3/4 in.) 20 cm (8 in.) Extension Set with luer activated needleless injection Y-site					
80.	21-3469-24	GRIPPER PLUS® POWER P.A.C. Needles: NDL, GRIPPER PLUS, PWR INJECTABLE, 1.1mm (19 G) x 25mm (1 in.) 20 cm (8 in.) Extension Set with luer activated needleless injection Y-site					
81.	21-3470-24	GRIPPER PLUS® POWER P.A.C. Needles: NDL, GRIPPER PLUS, PWR INJECTABLE, 1.1mm (19 G) x 32mm (1 1/4 in.) 20 cm (8 in.) Extension Set with luer activated needleless injection Y-site					

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Num	Catalog Number	Product Description	Manufacturing Site	UMDNS (if applicable)	GMDN Code	EU Risk Class	EU Rule
82.	21-3251-24	GRIPPER® Micro Blunt Cannula , Non-coring Safety Needles 0.7 mm (22 G) x 19mm (3/4 in.) 20 cm (8 in.) Extension Set without Y-Site	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4 Parque Industrial Internacional Tijuana, Baja California 22425 Mexico	N/A	17180	IIa	7
83.	21-3252-24	GRIPPER® Micro Blunt Cannula, Non-coring Safety Needles 0.7 mm (22 G) x 25mm (1 in.) 20 cm (8 in.) Extension Set without Y-Site					
84.	21-3253-24	GRIPPER® Micro Blunt Cannula, Non-coring Safety Needles: 0.7 mm (22 G) x 32mm (1 1/4 in.) 20 cm (8 in.) Extension Set without Y-Site					
85.	21-3256-24	GRIPPER® Micro Blunt Cannula, Non-coring Safety Needles: 0.9 mm (20 G) x 19mm (3/4 in.) 20 cm (8 in.) Extension Set without Y-Site					
86.	21-3257-24	GRIPPER® Micro Blunt Cannula, Non-coring Safety Needles: 0.9 mm (20 G) x 25mm (1 in.) 20 cm (8 in.) Extension Set without Y-Site					
87.	21-3258-24	GRIPPER® Micro Blunt Cannula, Non-coring Safety Needles: 0.9 mm (20 G) x 32mm (1 1/4 in.) 20 cm (8 in.) Extension Set without Y-Site					
88.	21-3260-24	GRIPPER® Micro Blunt Cannula, Non-coring Safety Needles: 1.1 mm (19 G) x 19mm (3/4 in.) 20 cm (8 in.) Extension Set without Y-Site					

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89.	21-3261-24	GRIPPER® Micro Blunt Cannula, Non-coring Safety Needles: 1.1 mm (19 G) x 25mm (1 in.) 20 cm (8 in.) Extension Set without Y-Site	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4 Parque Industrial Internacional Tijuana, Baja California 22425 Mexico	N/A	17180	IIa	7
90.	21-3262-24	GRIPPER® Micro Needles: 1.1 mm (19 G) x 32mm (1 1/4 in.) 20 cm (8 in.) Extension Set without Y-Site					
91.	21-3271-24	GRIPPER® Micro Blunt Cannula, Non-coring Safety Needles 0.7 mm (22 G) x 19mm (3/4 in.) 20 cm (8 in.) Extension Set with needleless Y-site					
92.	21-3272-24	GRIPPER® Micro Blunt Cannula, Non-coring Safety Needles 0.7 mm (22 G) x 25mm (1 in.) 20 cm (8 in.) Extension Set with needleless Y-site					
93.	21-3273-24	GRIPPER® Micro Blunt Cannula, Non-coring Safety Needles 0.7 mm (22 G) x 32mm (1 1/4 in.) 20 cm (8 in.) Extension Set with needleless Y-site					
94.	21-3276-24	GRIPPER® Micro Blunt Cannula, Non-coring Safety Needles 0.9 mm (20 G) x 19mm (3/4 in.) 20 cm (8 in.) Extension Set with needleless Y-site					
95.	21-3277-24	GRIPPER® Micro Blunt Cannula, Non-coring Safety Needles: 0.9 mm (20 G) x 25mm (1 in.) 20 cm (8 in.) Extension Set with needleless Y-site					
96.	21-3278-24	GRIPPER® Micro Blunt Cannula, Non-coring Safety Needles: 0.9 mm (20 G) x 32mm (1 1/4 in.) 20 cm (8 in.) Extension Set with needleless Y-site					



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97.	21-3280-24	GRIPPER® Micro Blunt Cannula, Non-coring Safety Needles 1.1 mm (19 G) x 19mm (3/4 in.) 20 cm (8 in.) Extension Set with needleless Y-site	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4 Parque Industrial Internacional Tijuana, Baja California 22425 Mexico	N/A	17180	IIa	7
98.	21-3281-24	GRIPPER® Micro Blunt Cannula, Non-coring Safety Needles 1.1 mm (19 G) x 25mm (1 in.) 20 cm (8 in.) Extension Set with needleless Y-site					
99.	21-3282-24	GRIPPER® Micro Blunt Cannula, Non-coring Safety Needles 1.1 mm (19 G) x 32mm (1 1/4 in.) 20 cm (8 in.) Extension Set with needleless Y-site					
100.	21-2005-24	PORT-A-CATH® 0,7mm (22G) x 25mm (1 in.), STRAIGHT					
101.	21-2006-24	PORT-A-CATH® 0,7mm (22G) x 25mm (1 in.), 90 DEG BENT					
102.	21-2007-24	PORT-A-CATH® 0,7mm (22G) x 38mm (1 1/2 in.), STRAIGHT					
103.	21-2008-24	PORT-A-CATH® 0,7mm (22G) x 38mm (1 1/2 in.), 90 DEG BENT					
104.	21-2013-24	PORT-A-CATH® 0,9mm (20G) x 25mm (1 in.), STRAIGHT					
105.	21-2014-24	PORT-A-CATH® 0,9mm (20G) x 25mm (1 in.), 90 DEG BENT					
106.	21-2015-24	PORT-A-CATH® 0,9mm (20G) x 38mm (1 1/2 in.), STRAIGHT					
107.	21-2016-24	PORT-A-CATH® 0,9mm (20G) x 38mm (1 1/2 in.), 90 DEG BENT					
108.	21-2021-24	PORT-A-CATH® 1,1mm (19G) x 25mm (1 in.), STRAIGHT					
109.	21-2022-24	PORT-A-CATH® 1,1mm (19G) x 25mm (1 in.), 90 DEG BENT					
110.	21-2026-24	PORT-A-CATH® 1,1mm (19G) x 38mm (1 1/2 in.), 90 DEG BENT					



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111.	21-2027-24	PORT-A-CATH® 1,1mm (19G) x 51mm (2 in.), STRAIGHT	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4 Parque Industrial Internacional Tijuana, Baja California 22425 Mexico	N/A	17180	IIa	7
112.	21-2287-24	PORT-A-CATH® 0.9mm (20G) x 19mm (3/4 in.), 90 DEG BENT					
113.	21-2316-24	PORT-A-CATH® 0.7mm (22G) x 13mm (1/2 in.), 90 DEG BENT					
114.	21-2317-24	PORT-A-CATH® 0.9mm (20G) x 13mm (1/2 in.), 90 DEG BENT					
115.	21-0125-24	SUBCUTANEOUS TUNNELING DEVICE			46801		

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Appendix 2: Revision History

Revision Number	Summary of Changes / Additions	Created / Revised by	Date (DD-MMM-YYYY Format)
001	Updated to new Template, Updated EC Cert Info	Mitchell Madsen	16-JAN-2017
002	The purpose of this revision update was in response to Notified Body Transfer. The changes to this DoC include: Notified Body name and number from Intertek 0473 to BSI 0086, the certificate number from 058-05 CE to CE 669121, and the revision from 001 to 002. No updates made to the content of this document, with the exception of change document number format from SXXX to DoCXXX (from S1144 to DoC-115) to load documents into Agile, added STED # to header for traceability to STED, removed product code 21-2003-24 as this product is obsolete and revision from 001 to 002.	Brent Pearson	01AUG2017
003	Updated the DoC to the latest template in Agile from Rev 002 to 003. Changed the Manufacturing Site from St. Paul to Tijuana for the following codes: 21-2320-24, 21-2340-24, 21-2386-24, 21-2470-24, 21-2471-24, 21-2472-24, 21-2476-24, 21-2477-24, 21-2478-24, 21-2479-24, 21-2480-24, 21-2481-24, 21-2714-24, 21-2005-24, 21-2006-24, 21-2007-24, 21-2008-24, 21-2013-24, 21-2014-24, 21-2015-24, 21-2016-24, 21-2021-24, 21-2022-24, 21-2026-24, 21-2027-24, 21-2287-24, 21-2316-24, 21-2317-24 and 21-0125-24. Changed the Authorized Signatory from Jim Taufen to Stacy Novak. Updated the Product Descriptions for all product codes in DoC to replicate Marketing Literature Description.	Mitchell Madsen	05-MAR-2018
104	The purpose of this revision is to align the product scope with the recertified EC certificate for Minneapolis, "Sterile Needles and Introducer for Implantable Access." Updated GMDN term for Subcutaneous Tunneling Tool	Dominique Neisz	10-AUG-2018