smiths medical bringing technology to life	**Declaration of Conformity** S1144: Port-A-Cath Accessories	DoC-115 Revision Number: 105

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):	Deltec® 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®
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: 09OCT2019

Name: Stacy Novak

Title: Director, Regulatory Operations

Location of Signatory: Minneapolis, MN, USA

Appendix 1: Product List

Num	Catalog Number	Product Description	Manufacturing Site	GMDN Code	EU Risk Class	EU Rule
1.	21-2320-24	SET, INTRODUCER, 6FR	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	58865	IIa	7
2.	21-2340-24	SET, INTRO, SUBCLAVIAN, 9FR	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	58865	IIa	7
3.	21-2386-24	SET, INTRO, SUBCLAVIAN, 11FR	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	58865	IIa	7
4.	21-2470-24	SET, INTRO, SUBCLAVIAN, 8.5F	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	58865	IIa	7
5.	21-2471-24	SET, INTRO, 7 FR	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	58865	IIa	7
6.	21-2472-24	SET, INTRO, 10Fr	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	58865	IIa	7
7.	21-2476-24	SET, INTRO, 6Fr, VALVED	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	58865	IIa	7

Num	Catalog Number	Product Description	Manufacturing Site	GMDN Code	EU Risk Class	EU Rule
8.	21-2477-24	SET, INTRO 7 Fr, VALVED	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	58865	IIa	7
9.	21-2478-24	SET, INTRO 8.5Fr, VALVED	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	58865	IIa	7
10.	21-2479-24	SET, INTRO 9 Fr, VALVED	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	58865	IIa	7
11.	21-2480-24	SET, INTRO 10Fr, VALVED	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	58865	IIa	7
12.	21-2481-24	SET, INTRO 11Fr, VALVED	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	58865	IIa	7
13.	21-2714-24	NDL, GRIPPER, 22G X 1" (25MM)	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	17701	IIa	7
14.	21-2715-24	NDL, GRIPPER, 22G X 1.25" (32MM)	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	17701	IIa	7

Num	Catalog Number	Product Description	Manufacturing Site	GMDN Code	EU Risk Class	EU Rule
15.	21-2717-24	NDL, GRIPPER, 20G X 1" (25MM)	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	17701	IIa	7
16.	21-2718-24	NDL, GRIPPER, 20G X 1.25" (32MM)	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	17701	IIa	7
17.	21-2720-24	NDL, GRIPPER, 19G X 1" (25MM)	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	17701	IIa	7
18.	21-2721-24	NDL, GRIPPER, 19G X 1.25" (32MM)	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	17701	IIa	7
19.	21-2733-24	NDL, GRIPPER, 22G X .75" (19MM)	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	17701	IIa	7
20.	21-2734-24	NDL, GRIPPER, 20G X .75" (19MM)	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	17701	IIa	7
21.	21-2735-24	NDL, GRIPPER, 19G X .75" (19MM)	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	17701	IIa	7

Num	Catalog Number	Product Description	Manufacturing Site	GMDN Code	EU Risk Class	EU Rule
22.	21-2736-24	NDL, GRIPPER, 20G X .625" (16MM)	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	17701	IIa	7
23.	21-2737-24	NDL, GRIPPER, 22G X .625" (16MM)	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	17701	IIa	7
24.	21-2760-24	NDL, GRIPPER PLUS, 22G X 1" (25MM)	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	17701	IIa	7
25.	21-2761-24	NDL, GRIPPER PLUS, 22G X 1.25" (32MM)	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	17701	IIa	7
26.	21-2762-24	NDL, GRIPPER PLUS, 20G X 1" (25MM)	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	17701	IIa	7
27.	21-2763-24	NDL, GRIPPER PLUS, 20G X 1.25" (32MM)	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	17701	IIa	7
28.	21-2764-24	NDL, GRIPPER PLUS, 19G X 1" (25MM)	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	17701	IIa	7

Num	Catalog Number	Product Description	Manufacturing Site	GMDN Code	EU Risk Class	EU Rule
29.	21-2765-24	NDL, GRIPPER PLUS, 19G X 1.25" (32MM)	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	17701	IIa	7
30.	21-2766-24	NDL, GRIPPER PLUS, 22G X .75" (19MM)	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	17701	IIa	7
31.	21-2767-24	NDL, GRIPPER PLUS, 20G X .75" (19MM)	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	17701	IIa	7
32.	21-2768-24	NDL, GRIPPER PLUS, 19G X .75" (19MM)	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	17701	IIa	7
33.	21-2769-24	NDL, GRIPPER PLUS, 20G X .625" (16MM)	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	17701	IIa	7
34.	21-2770-24	NDL, GRIPPER PLUS, 22G X .625" (16MM)	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	17701	IIa	7
35.	21-2860-24	NDL, GRIPPER PLUS, 22G X .625" (16MM), Y-SITE	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	17701	IIa	7

Num	Catalog Number	Product Description	Manufacturing Site	GMDN Code	EU Risk Class	EU Rule
36.	21-2861-24	NDL, GRIPPER PLUS, 22G X .75" (19MM), Y-SITE	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	17701	IIa	7
37.	21-2862-24	NDL, GRIPPER PLUS, 22G X 1" (25MM), Y-SITE	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	17701	IIa	7
38.	21-2863-24	NDL, GRIPPER PLUS, 22G X 1.25" (32MM), Y-SITE	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	17701	IIa	7
39.	21-2864-24	NDL, GRIPPER PLUS, 20G X .625" (16MM), Y-SITE	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	17701	IIa	7
40.	21-2865-24	NDL, GRIPPER PLUS, 20G X .75" (19MM), Y-SITE	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	17701	IIa	7
41.	21-2866-24	NDL, GRIPPER PLUS, 20G X 1" (25MM), Y-SITE	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	17701	IIa	7
42.	21-2867-24	NDL, GRIPPER PLUS, 20G X 1.25" (32MM), Y-SITE	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	17701	IIa	7

Num	Catalog Number	Product Description	Manufacturing Site	GMDN Code	EU Risk Class	EU Rule
43.	21-2868-24	NDL, GRIPPER PLUS, 19G X .75" (19MM), Y-SITE	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	17701	IIa	7
44.	21-2869-24	NDL, GRIPPER PLUS, 19G X 1" (25MM), Y-SITE	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	17701	IIa	7
45.	21-2870-24	NDL, GRIPPER PLUS, 19G X 1.25" (32MM), Y-SITE	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	17701	IIa	7
46.	21-2938-24	NDL, GRIPPER, 22G X .625" (16MM), Y-SITE	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	17701	IIa	7
47.	21-2939-24	NDL, GRIPPER, 22G X .75" (19MM), Y-SITE	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	17701	IIa	7
48.	21-2940-24	NDL, GRIPPER, 22G X 1" (25MM), Y-SITE	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	17701	IIa	7
49.	21-2941-24	NDL, GRIPPER, 22G X 1.25" (32MM), Y-SITE	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	17701	IIa	7

Num	Catalog Number	Product Description	Manufacturing Site	GMDN Code	EU Risk Class	EU Rule
50.	21-2946-24	NDL, GRIPPER, 20G X .625" (16MM), Y-SITE	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	17701	IIa	7
51.	21-2947-24	NDL, GRIPPER, 20G X .75" (19MM), Y-SITE	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	17701	IIa	7
52.	21-2948-24	NDL, GRIPPER, 20G X 1" (25MM), Y-SITE	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	17701	IIa	7
53.	21-2949-24	NDL, GRIPPER, 20G X 1.25" (32MM), Y-SITE	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	17701	IIa	7
54.	21-2955-24	NDL, GRIPPER, 19G X .75" (19MM), Y-SITE	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	17701	IIa	7
55.	21-2956-24	NDL, GRIPPER, 19G X 1" (25MM), Y-SITE	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	17701	IIa	7
56.	21-2957-24	NDL, GRIPPER, 19G X 1.25" (32MM), Y-SITE	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	17701	IIa	7

Num	Catalog Number	Product Description	Manufacturing Site	GMDN Code	EU Risk Class	EU Rule
57.	21-2960-24	NDL, GRIPPER PLUS, 22G X .625" (16MM), NEEDLELESS Y-SITE	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	17701	IIa	7
58.	21-2961-24	NDL, GRIPPER PLUS, 22G X .75" (19MM), NEEDLELESS Y-SITE	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	17701	IIa	7
59.	21-2962-24	NDL, GRIPPER PLUS, 22G X 1" (25MM), NEEDLELESS Y-SITE	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	17701	IIa	7
60.	21-2963-24	NDL, GRIPPER PLUS, 22G X 1.25" (32MM), NEEDLELESS Y-SITE	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	17701	IIa	7
61.	21-2964-24	NDL, GRIPPER PLUS, 20G X .625" (16MM), NEEDLESS Y-SITE	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	17701	IIa	7
62.	21-2965-24	NDL, GRIPPER PLUS, 20G X .75" (19MM), NEEDLELESS Y-SITE	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	17701	IIa	7
63.	21-2966-24	NDL, GRIPPER PLUS, 20G X 1" (25MM), NEEDLELESS Y-SITE	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	17701	IIa	7

Num	Catalog Number	Product Description	Manufacturing Site	GMDN Code	EU Risk Class	EU Rule
64.	21-2967-24	NDL, GRIPPER PLUS, 20G X 1.25" (32MM), NEEDLELESS Y-SITE	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	17701	IIa	7
65.	21-2968-24	NDL, GRIPPER PLUS, 19G X .75" (19MM), NEEDLELESS Y-SITE	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	17701	IIa	7
66.	21-2969-24	NDL, GRIPPER PLUS, 19G X 1" (25MM), NEEDLELESS Y-SITE	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	17701	IIa	7
67.	21-2970-24	NDL, GRIPPER PLUS, 19G X 1.25" (32MM), NEEDLELESS Y-SITE	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	17701	IIa	7
68.	21-3362-24	NDL, GRIPPER PLUS, PWR INJECTABLE, 20G X 1"	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	17701	IIa	7
69.	21-3363-24	NDL, GRIPPER PLUS, PWR INJECTABLE, 20G X 1.25"	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	17701	IIa	7
70.	21-3364-24	NDL, GRIPPER PLUS, PWR INJECTABLE, 19G X 1"	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	17701	IIa	7

Num	Catalog Number	Product Description	Manufacturing Site	GMDN Code	EU Risk Class	EU Rule
71.	21-3365-24	NDL, GRIPPER PLUS, PWR INJECTABLE, 19G X 1.25"	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	17701	IIa	7
72.	21-3367-24	NDL, GRIPPER PLUS, PWR INJECTABLE, 20G X .75"	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	17701	IIa	7
73.	21-3368-24	NDL, GRIPPER PLUS, PWR INJECTABLE, 19G X .75"	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	17701	IIa	7
74.	21-3369-24	NDL, GRIPPER PLUS, PWR INJECTABLE, 20G X .625"	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	17701	IIa	7
75.	21-3464-24	NDL, GRIPPER PLUS, PWR INJECTABLE, 20G X .625", NEEDLELESS Y-SITE	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	17701	IIa	7
76.	21-3465-24	NDL, GRIPPER PLUS, PWR INJECTABLE, 20G X .75", NEEDLELESS Y-SITE	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	17701	IIa	7
77.	21-3466-24	NDL, GRIPPER PLUS, PWR INJECTABLE, 20G X 1", NEEDLELESS Y-SITE	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	17701	IIa	7

Num	Catalog Number	Product Description	Manufacturing Site	GMDN Code	EU Risk Class	EU Rule
78.	21-3467-24	NDL, GRIPPER PLUS, PWR INJECTABLE, 20G X 1.25", NEEDLELESS Y-SITE	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	17701	IIa	7
79.	21-3468-24	NDL, GRIPPER PLUS, PWR INJECTABLE, 19G X .75", NEEDLELESS Y-SITE	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	17701	IIa	7
80.	21-3469-24	NDL, GRIPPER PLUS, PWR INJECTABLE, 19G X 1", NEEDLELESS Y-SITE	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	17701	IIa	7
81.	21-3470-24	NDL, GRIPPER PLUS, PWR INJECTABLE, 19G X 1.25", NEEDLELESS Y-SITE	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	17701	IIa	7
82.	21-3251-24	NDL, GRIPPER MICRO, 22G X .75	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	17701	IIa	7
83.	21-3252-24	NDL, GRIPPER MICRO, 22G X 1"	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	17701	IIa	7
84.	21-3253-24	NDL, GRIPPER MICRO, 22G X 1.25"	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	17701	IIa	7

Num	Catalog Number	Product Description	Manufacturing Site	GMDN Code	EU Risk Class	EU Rule
85.	21-3256-24	NDL, GRIPPER MICRO, 20G X .75"	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	17701	IIa	7
86.	21-3257-24	NDL, GRIPPER MICRO, 20G X 1"	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	17701	IIa	7
87.	21-3258-24	NDL, GRIPPER MICRO, 20G X 1.25"	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	17701	IIa	7
88.	21-3260-24	NDL, GRIPPER MICRO, 19G X .75"	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	17701	IIa	7
89.	21-3261-24	NDL, GRIPPER MICRO, 19G X 1"	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	17701	IIa	7
90.	21-3262-24	NDL, GRIPPER MICRO, 19G X 1.25"	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	17701	IIa	7
91.	21-3271-24	NDL, GRIPPER MICRO, 22G X .75", LUER ACTIVATED NEEDLELESS Y-SITE	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	17701	IIa	7

Num	Catalog Number	Product Description	Manufacturing Site	GMDN Code	EU Risk Class	EU Rule
92.	21-3272-24	NDL, GRIPPER MICRO, 22G X 1", LUER ACTIVATED NEEDLELESS Y-SITE	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	17701	IIa	7
93.	21-3273-24	NDL, GRIPPER MICRO, 22G X 1.25", NAC Y-SITE	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	17701	IIa	7
94.	21-3276-24	NDL, GRIPPER MICRO, 20G X .75", LUER ACTIVATED NEEDLELESS Y-SITE	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	17701	IIa	7
95.	21-3277-24	NDL, GRIPPER MICRO, 20G X 1", LUER ACTIVATED NEEDLELESS Y-SITE	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	17701	IIa	7
96.	21-3278-24	NDL, GRIPPER MICRO, 20G X 1.25", NAC Y-SITE	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	17701	IIa	7
97.	21-3280-24	NDL, GRIPPER MICRO, 19G X .75", LUER ACTIVATED NEEDLELESS Y-SITE	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	17701	IIa	7
98.	21-3281-24	NDL, GRIPPER MICRO, 19G X 1", LUER ACTIVATED NEEDLELESS Y-SITE	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	17701	IIa	7

Num	Catalog Number	Product Description	Manufacturing Site	GMDN Code	EU Risk Class	EU Rule
99.	21-3282-24	NDL, GRIPPER MICRO, 19G X 1.25", NAC Y-SITE	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	17701	IIa	7
100.	21-2005-24	NDL, PH, 0.7MM (22G) X 25MM (1 IN.), STRAIGHT	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	17180	IIa	7
101.	21-2006-24	NDL, PH, 0.7MM (22G) X 25MM (1 IN.), 90 DEG BENT	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	17180	IIa	7
102.	21-2007-24	NDL, PH, 0.7MM (22G) X 38MM (1-1/2 IN.), STRAIGHT	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	17180	IIa	7
103.	21-2008-24	NDL, PH, 0.7MM (22G) X 38MM (1-1/2 IN.), 90 DEG BENT	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	17180	IIa	7
104.	21-2013-24	NDL, PH, 0.9MM (20G) X 25MM (1 IN.), STRAIGHT	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	17180	IIa	7
105.	21-2014-24	NDL, PH, 0.9MM (20G) X 25MM (1 IN.), 90 DEG BENT	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	17180	IIa	7

Num	Catalog Number	Product Description	Manufacturing Site	GMDN Code	EU Risk Class	EU Rule
106.	21-2015-24	NDL, PH, 0.9MM (20G) X 38MM (1-1/2 IN.), STRAIGHT	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	17180	IIa	7
107.	21-2016-24	NDL, PH, 0.9MM (20G) X 38MM (1-1/2 IN.), 90 DEG BENT	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	17180	IIa	7
108.	21-2021-24	NDL, PH, 1.1MM (19G) X 25MM (1 IN.), STRAIGHT	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	17180	IIa	7
109.	21-2022-24	NDL, PH, 1.1MM (19G) X 25MM (1IN.), 90 DEG BENT	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	17180	IIa	7
110.	21-2026-24	NDL, PH, 1.1MM (19G) X 38MM (1-1/2IN.), 90 DEG BENT	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	17180	IIa	7
111.	21-2027-24	NDL, PH, 1.1MM (19G) X 51MM (2 IN.), STRAIGHT	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	17180	IIa	7
112.	21-2287-24	NDL, PH, 0.9MM (20G) X 19MM (3/4 IN.), 90 DEG BENT	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	17180	IIa	7

Num	Catalog Number	Product Description	Manufacturing Site	GMDN Code	EU Risk Class	EU Rule
113.	21-2316-24	NDL, PH, 0.7MM (22G) X 13MM (1/2 IN.), 90 DEG BENT	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	17180	IIa	7
114.	21-2317-24	NDL, PH, 0.9MM (20G) X 13MM (1/2 IN.), 90 DEG BENT	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	17180	IIa	7
115.	21-0125-24	SUBCUTANEOUS TUNNELING DEV	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	46801	IIa	7

Appendix 2: Revision History

Revision Number	Summary of Changes / Additions	Created / Revised by	Date
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	01-AUG-2017
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
105	-Updated the DoC to the latest template in Agile from Rev 003 to 105 -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	Mitchell Madsen	07-OCT-2019

Revision Number	Summary of Changes / Additions	Created / Revised by	Date
	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 the Netherlands due to Brexit. The EC Certificate number remains the same. -Added “Deltec®” as a tradename as the SKUs listed on this DoC are Deltec® Port-A-Cath. -Updated the Product Descriptions of the Catalog Numbers in Appendix 1 to match their Descriptions in Agile -Changed the Tijuana Manufacturing Site address to match EC Certificate 669121. -GMDN Code in Appendix 1 was updated for the following SKUs to better match product description and intended use: 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 from 17180 to 58865; 21-2714-24, 21-2715-24, 21-2717-24, 21-2718-24, 21-2720-24, 21-2721-24, 21-2733-24, 21-2734-24, 21-2735-24, 21-2736-24, 21-2737-24, 21-2938-24, 21-2939-24, 21-2940-24, 21-2941-24, 21-2946-24, 21-2947-24, 21-2948-24, 21-2949-24, 21-2955-24, 21-2956-24, 21-2957-24, 21-2760-24, 21-2761-24, 21-2762-24, 21-2763-24, 21-2764-24, 21-2765-24, 21-2766-24, 21-2767-24, 21-2768-24, 21-2769-24, 21-2770-24, 21-2860-24, 21-2861-24, 21-2862-24, 21-2863-24, 21-2864-24, 21-2865-24, 21-2866-24, 21-2867-24, 21-2868-24, 21-2869-24, 21-2870-24, 21-2960-24, 21-2961-24, 21-2962-24, 21-2963-24, 21-2964-24, 21-2965-24, 21-2966-24, 21-2967-24, 21-2968-24, 21-2969-24, 21-2970-24, 21-3362-24, 21-3363-24, 21-3364-24, 21-3365-24, 21-3367-24, 21-3368-24, 21-3369-24, 21-3464-24, 21-3465-24, 21-3466-24, 21-3467-24, 21-3468-24, 21-3469-24, 21-3470-24, 21-3251-24, 21-3252-24, 21-3253-24, 21-3256-24, 21-3257-24, 21-3258-24		

Revision Number	Summary of Changes / Additions	Created / Revised by	Date
	21-3260-24, 21-3261-24, 21-3262-24,21-3271-24, 21-3272-24, 21-3273-24, 21-3276-24, 21-3277-24, 21-3278-24, 21-3280-24, 21-3281-24, 21-3282-24 from 17180 to 17701.		