

	Declaration of Conformity	DoC-115 Revision Number: 105
	S1144: Port-A-Cath Accessories	

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: 09 OCT 2019

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	Ila	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	Ila	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	Ila	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	Ila	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	Ila	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	Ila	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	Ila	7

Declaration of Conformity

DoC-115

Revision Number: 105

S1144: Port-A-Cath Accessories

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	Ila	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	Ila	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	Ila	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	Ila	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	Ila	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	Ila	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	Ila	7

Declaration of Conformity

DoC-115

Revision Number: 105

S1144: Port-A-Cath Accessories

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	Ila	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	Ila	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	Ila	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	Ila	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	Ila	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	Ila	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	Ila	7

Declaration of Conformity

DoC-115

Revision Number: 105

S1144: Port-A-Cath Accessories

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	Ila	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	Ila	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	Ila	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	Ila	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	Ila	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	Ila	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	Ila	7

Declaration of Conformity

DoC-115

Revision Number: 105

S1144: Port-A-Cath Accessories

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	Ila	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	Ila	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	Ila	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	Ila	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	Ila	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	Ila	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	Ila	7

Declaration of Conformity

DoC-115

Revision Number: 105

S1144: Port-A-Cath Accessories

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	Ila	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	Ila	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	Ila	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	Ila	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	Ila	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	Ila	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	Ila	7

Declaration of Conformity

DoC-115

Revision Number: 105

S1144: Port-A-Cath Accessories

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	Ila	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	Ila	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	Ila	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	Ila	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	Ila	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	Ila	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	Ila	7

Declaration of Conformity

DoC-115

Revision Number: 105

S1144: Port-A-Cath Accessories

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	Ila	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	Ila	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	Ila	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	Ila	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	Ila	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	Ila	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	Ila	7

Declaration of Conformity

DoC-115

Revision Number: 105

S1144: Port-A-Cath Accessories

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	Ila	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	Ila	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	Ila	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	Ila	7
61.	21-2964-24	NDL, GRIPPER PLUS, 20G 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	Ila	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	Ila	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	Ila	7

Declaration of Conformity

DoC-115

Revision Number: 105

S1144: Port-A-Cath Accessories

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	Ila	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	Ila	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	Ila	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	Ila	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	Ila	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	Ila	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	Ila	7

Declaration of Conformity

DoC-115

Revision Number: 105

S1144: Port-A-Cath Accessories

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	Ila	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	Ila	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	Ila	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	Ila	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	Ila	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	Ila	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	Ila	7

Declaration of Conformity

DoC-115

Revision Number: 105

S1144: Port-A-Cath Accessories

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	Ila	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	Ila	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	Ila	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	Ila	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	Ila	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	Ila	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	Ila	7

Declaration of Conformity

DoC-115

Revision Number: 105

S1144: Port-A-Cath Accessories

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	Ila	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	Ila	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	Ila	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	Ila	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	Ila	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	Ila	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	Ila	7

Declaration of Conformity

DoC-115

Revision Number: 105

S1144: Port-A-Cath Accessories

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	Ila	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	Ila	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	Ila	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	Ila	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	Ila	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	Ila	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	Ila	7

Declaration of Conformity

DoC-115

Revision Number: 105

S1144: Port-A-Cath Accessories

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	Ila	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	Ila	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	Ila	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	Ila	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	Ila	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	Ila	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	Ila	7

Declaration of Conformity

DoC-115

Revision Number: 105

S1144: Port-A-Cath Accessories

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	Ila	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	Ila	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	Ila	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	Ila	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	Ila	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	Ila	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	Ila	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	Ila	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	Ila	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	Ila	7