	<b>Declaration of Conformity</b>	DoC-115 Revision Number: 107
	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: 

Date: 23 JUNE 2022

Name: Kate Stephany

Title: Manager, Regulatory Affairs


Location of Signatory: Minneapolis, MN, USA

 <small>bringing technology to life</small>	<b>Declaration of Conformity</b>	DoC-115 Revision Number: 107
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**Appendix 1: Product List:**


No.	Product Code	Product Description	GMDN Code	EU Risk Class	EU Rule
1.	21-0125-24	Subcutaneous Tunneling Device	46801	Ila	7
2.	21-2320-24	Peel Away Introducer Set	58865	Ila	7
3.	21-2340-24	Peel Away Introducer Set	58865	Ila	7
4.	21-2386-24	Peel Away Introducer Set	58865	Ila	7
5.	21-2470-24	Peel Away Introducer Set	58865	Ila	7
6.	21-2471-24	Peel Away Introducer Set	58865	Ila	7
7.	21-2472-24	Peel Away Introducer Set	58865	Ila	7
8.	21-2476-24	Peel Away Introducer Set	58865	Ila	7
9.	21-2477-24	Peel Away Introducer Set	58865	Ila	7
10.	21-2478-24	Peel Away Introducer Set	58865	Ila	7
11.	21-2479-24	Peel Away Introducer Set	58865	Ila	7
12.	21-2480-24	Peel Away Introducer Set	58865	Ila	7
13.	21-2481-24	Peel Away Introducer Set	58865	Ila	7
14.	21-2005-24	Deltec® PORT-A-CATH® Plastic Hub Needles	17701	Ila	7
15.	21-2006-24	Deltec® PORT-A-CATH® Plastic Hub Needles	17701	Ila	7
16.	21-2007-24	Deltec® PORT-A-CATH® Plastic Hub Needles	17701	Ila	7
17.	21-2008-24	Deltec® PORT-A-CATH® Plastic Hub Needles	17701	Ila	7
18.	21-2013-24	Deltec® PORT-A-CATH® Plastic Hub Needles	17701	Ila	7
19.	21-2014-24	Deltec® PORT-A-CATH® Plastic Hub Needles	17701	Ila	7
20.	21-2015-24	Deltec® PORT-A-CATH® Plastic Hub Needles	17701	Ila	7

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No.	Product Code	Product Description	GMDN Code	EU Risk Class	EU Rule
21.	21-2016-24	Deltec® PORT-A-CATH® Plastic Hub Needles	17701	Ila	7
22.	21-2021-24	Deltec® PORT-A-CATH® Plastic Hub Needles	17701	Ila	7
23.	21-2022-24	Deltec® PORT-A-CATH® Plastic Hub Needles	17701	Ila	7
24.	21-2026-24	Deltec® PORT-A-CATH® Plastic Hub Needles	17701	Ila	7
25.	21-2027-24	Deltec® PORT-A-CATH® Plastic Hub Needles	17701	Ila	7
26.	21-2287-24	Deltec® PORT-A-CATH® Plastic Hub Needles	17701	Ila	7
27.	21-2316-24	Deltec® PORT-A-CATH® Plastic Hub Needles	17701	Ila	7
28.	21-2317-24	Deltec® PORT-A-CATH® Plastic Hub Needles	17701	Ila	7
29.	21-3362-24	GRIPPER PLUS® POWER P.A.C. Non-Coring Safety Needle for Power Injection	17701	Ila	7
30.	21-3363-24	GRIPPER PLUS® POWER P.A.C. Non-Coring Safety Needle for Power Injection	17701	Ila	7
31.	21-3364-24	GRIPPER PLUS® POWER P.A.C. Non-Coring Safety Needle for Power Injection	17701	Ila	7
32.	21-3365-24	GRIPPER PLUS® POWER P.A.C. Non-Coring Safety Needle for Power Injection	17701	Ila	7
33.	21-3367-24	GRIPPER PLUS® POWER P.A.C. Non-Coring Safety Needle for Power Injection	17701	Ila	7
34.	21-3368-24	GRIPPER PLUS® POWER P.A.C. Non-Coring Safety Needle for Power Injection	17701	Ila	7
35.	21-3369-24	GRIPPER PLUS® POWER P.A.C. Non-Coring Safety Needle for Power Injection	17701	Ila	7
36.	21-3464-24	GRIPPER PLUS® POWER P.A.C. Non-Coring Safety Needle for Power Injection	17701	Ila	7
37.	21-3465-24	GRIPPER PLUS® POWER P.A.C. Non-Coring Safety Needle for Power Injection	17701	Ila	7
38.	21-3466-24	GRIPPER PLUS® POWER P.A.C. Non-Coring Safety Needle for Power Injection	17701	Ila	7
39.	21-3467-24	GRIPPER PLUS® POWER P.A.C. Non-Coring Safety Needle for Power Injection	17701	Ila	7
40.	21-3468-24	GRIPPER PLUS® POWER P.A.C. Non-Coring Safety Needle for Power Injection	17701	Ila	7
41.	21-3469-24	GRIPPER PLUS® POWER P.A.C. Non-Coring Safety Needle for Power Injection	17701	Ila	7

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No.	Product Code	Product Description	GMDN Code	EU Risk Class	EU Rule
42.	21-3470-24	GRIPPER PLUS® POWER P.A.C. Non-Coring Safety Needle for Power Injection	17701	Ila	7
43.	21-3251-24	Gripper Micro® Blunt Cannula, Non-Coring Safety Needle	17701	Ila	7
44.	21-3252-24	Gripper Micro® Blunt Cannula, Non-Coring Safety Needle	17701	Ila	7
45.	21-3253-24	Gripper Micro® Blunt Cannula, Non-Coring Safety Needle	17701	Ila	7
46.	21-3256-24	Gripper Micro® Blunt Cannula, Non-Coring Safety Needle	17701	Ila	7
47.	21-3257-24	Gripper Micro® Blunt Cannula, Non-Coring Safety Needle	17701	Ila	7
48.	21-3258-24	Gripper Micro® Blunt Cannula, Non-Coring Safety Needle	17701	Ila	7
49.	21-3260-24	Gripper Micro® Blunt Cannula, Non-Coring Safety Needle	17701	Ila	7
50.	21-3261-24	Gripper Micro® Blunt Cannula, Non-Coring Safety Needle	17701	Ila	7
51.	21-3262-24	Gripper Micro® Blunt Cannula, Non-Coring Safety Needle	17701	Ila	7
52.	21-3271-24	Gripper Micro® Blunt Cannula, Non-Coring Safety Needle	17701	Ila	7
53.	21-3272-24	Gripper Micro® Blunt Cannula, Non-Coring Safety Needle	17701	Ila	7
54.	21-3273-24	Gripper Micro® Blunt Cannula, Non-Coring Safety Needle	17701	Ila	7
55.	21-3276-24	Gripper Micro® Blunt Cannula, Non-Coring Safety Needle	17701	Ila	7
56.	21-3277-24	Gripper Micro® Blunt Cannula, Non-Coring Safety Needle	17701	Ila	7
57.	21-3278-24	Gripper Micro® Blunt Cannula, Non-Coring Safety Needle	17701	Ila	7
58.	21-3280-24	Gripper Micro® Blunt Cannula, Non-Coring Safety Needle	17701	Ila	7
59.	21-3281-24	Gripper Micro® Blunt Cannula, Non-Coring Safety Needle	17701	Ila	7
60.	21-3282-24	Gripper Micro® Blunt Cannula, Non-Coring Safety Needle	17701	Ila	7
61.	21-2760-24	Gripper Plus® Non-coring Safety Needle Extension Set	17701	Ila	7
62.	21-2761-24	Gripper Plus® Non-coring Safety Needle Extension Set	17701	Ila	7

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No.	Product Code	Product Description	GMDN Code	EU Risk Class	EU Rule
63.	21-2762-24	Gripper Plus® Non-coring Safety Needle Extension Set	17701	Ila	7
64.	21-2763-24	Gripper Plus® Non-coring Safety Needle Extension Set	17701	Ila	7
65.	21-2764-24	Gripper Plus® Non-coring Safety Needle Extension Set	17701	Ila	7
66.	21-2765-24	Gripper Plus® Non-coring Safety Needle Extension Set	17701	Ila	7
67.	21-2766-24	Gripper Plus® Non-coring Safety Needle Extension Set	17701	Ila	7
68.	21-2767-24	Gripper Plus® Non-coring Safety Needle Extension Set	17701	Ila	7
69.	21-2768-24	Gripper Plus® Non-coring Safety Needle Extension Set	17701	Ila	7
70.	21-2769-24	Gripper Plus® Non-coring Safety Needle Extension Set	17701	Ila	7
71.	21-2770-24	Gripper Plus® Non-coring Safety Needle Extension Set	17701	Ila	7
72.	21-2860-24	Gripper Plus® Non-coring Safety Needle Extension Set	17701	Ila	7
73.	21-2861-24	Gripper Plus® Non-coring Safety Needle Extension Set	17701	Ila	7
74.	21-2862-24	Gripper Plus® Non-coring Safety Needle Extension Set	17701	Ila	7
75.	21-2863-24	Gripper Plus® Non-coring Safety Needle Extension Set	17701	Ila	7
76.	21-2864-24	Gripper Plus® Non-coring Safety Needle Extension Set	17701	Ila	7
77.	21-2865-24	Gripper Plus® Non-coring Safety Needle Extension Set	17701	Ila	7
78.	21-2866-24	Gripper Plus® Non-coring Safety Needle Extension Set	17701	Ila	7
79.	21-2867-24	Gripper Plus® Non-coring Safety Needle Extension Set	17701	Ila	7
80.	21-2868-24	Gripper Plus® Non-coring Safety Needle Extension Set	17701	Ila	7
81.	21-2869-24	Gripper Plus® Non-coring Safety Needle Extension Set	17701	Ila	7
82.	21-2870-24	Gripper Plus® Non-coring Safety Needle Extension Set	17701	Ila	7
83.	21-2960-24	Gripper Plus® Non-coring Safety Needle Extension Set	17701	Ila	7

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No.	Product Code	Product Description	GMDN Code	EU Risk Class	EU Rule
84.	21-2961-24	Gripper Plus® Non-coring Safety Needle Extension Set	17701	Ila	7
85.	21-2962-24	Gripper Plus® Non-coring Safety Needle Extension Set	17701	Ila	7
86.	21-2963-24	Gripper Plus® Non-coring Safety Needle Extension Set	17701	Ila	7
87.	21-2964-24	Gripper Plus® Non-coring Safety Needle Extension Set	17701	Ila	7
88.	21-2965-24	Gripper Plus® Non-coring Safety Needle Extension Set	17701	Ila	7
89.	21-2966-24	Gripper Plus® Non-coring Safety Needle Extension Set	17701	Ila	7
90.	21-2967-24	Gripper Plus® Non-coring Safety Needle Extension Set	17701	Ila	7
91.	21-2968-24	Gripper Plus® Non-coring Safety Needle Extension Set	17701	Ila	7
92.	21-2969-24	Gripper Plus® Non-coring Safety Needle Extension Set	17701	Ila	7
93.	21-2970-24	Gripper Plus® Non-coring Safety Needle Extension Set	17701	Ila	7
94.	21-2714-24	Gripper® Non-Coring Needle Extension Set	17701	Ila	7
95.	21-2715-24	Gripper® Non-Coring Needle Extension Set	17701	Ila	7
96.	21-2717-24	Gripper® Non-Coring Needle Extension Set	17701	Ila	7
97.	21-2718-24	Gripper® Non-Coring Needle Extension Set	17701	Ila	7
98.	21-2720-24	Gripper® Non-Coring Needle Extension Set	17701	Ila	7
99.	21-2721-24	Gripper® Non-Coring Needle Extension Set	17701	Ila	7
100.	21-2733-24	Gripper® Non-Coring Needle Extension Set	17701	Ila	7
101.	21-2734-24	Gripper® Non-Coring Needle Extension Set	17701	Ila	7
102.	21-2735-24	Gripper® Non-Coring Needle Extension Set	17701	Ila	7
103.	21-2736-24	Gripper® Non-Coring Needle Extension Set	17701	Ila	7
104.	21-2737-24	Gripper® Non-Coring Needle Extension Set	17701	Ila	7

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No.	Product Code	Product Description	GMDN Code	EU Risk Class	EU Rule
105.	21-2938-24	Gripper® Non-Coring Needle Extension Set	17701	Ila	7
106.	21-2939-24	Gripper® Non-Coring Needle Extension Set	17701	Ila	7
107.	21-2940-24	Gripper® Non-Coring Needle Extension Set	17701	Ila	7
108.	21-2941-24	Gripper® Non-Coring Needle Extension Set	17701	Ila	7
109.	21-2946-24	Gripper® Non-Coring Needle Extension Set	17701	Ila	7
110.	21-2947-24	Gripper® Non-Coring Needle Extension Set	17701	Ila	7
111.	21-2948-24	Gripper® Non-Coring Needle Extension Set	17701	Ila	7
112.	21-2949-24	Gripper® Non-Coring Needle Extension Set	17701	Ila	7
113.	21-2955-24	Gripper® Non-Coring Needle Extension Set	17701	Ila	7
114.	21-2956-24	Gripper® Non-Coring Needle Extension Set	17701	Ila	7
115.	21-2957-24	Gripper® Non-Coring Needle Extension Set	17701	Ila	7

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