

|                                                                                   |                                  |                                 |
|-----------------------------------------------------------------------------------|----------------------------------|---------------------------------|
|  | <b>Declaration of Conformity</b> | DoC-115<br>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



**Declaration of Conformity**

S1144: Port-A-Cath Accessories

DoC-115  
Revision Number: 105

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.<br>de C.V.<br>Avenida Calidad No. 4, Industrial<br>Internacional Tijuana, Tijuana, B.C. C.P.<br>22425 Mexico | 58865     | Ila           | 7       |
| 2.  | 21-2340-24     | SET, INTRO, SUBCLAVIAN, 9FR  | Smiths Healthcare Manufacturing S.A.<br>de C.V.<br>Avenida Calidad No. 4, Industrial<br>Internacional Tijuana, Tijuana, B.C. C.P.<br>22425 Mexico | 58865     | Ila           | 7       |
| 3.  | 21-2386-24     | SET, INTRO, SUBCLAVIAN, 11FR | Smiths Healthcare Manufacturing S.A.<br>de C.V.<br>Avenida Calidad No. 4, Industrial<br>Internacional Tijuana, Tijuana, B.C. C.P.<br>22425 Mexico | 58865     | Ila           | 7       |
| 4.  | 21-2470-24     | SET, INTRO, SUBCLAVIAN, 8.5F | Smiths Healthcare Manufacturing S.A.<br>de C.V.<br>Avenida Calidad No. 4, Industrial<br>Internacional Tijuana, Tijuana, B.C. C.P.<br>22425 Mexico | 58865     | Ila           | 7       |
| 5.  | 21-2471-24     | SET, INTRO, 7 FR             | Smiths Healthcare Manufacturing S.A.<br>de C.V.<br>Avenida Calidad No. 4, Industrial<br>Internacional Tijuana, Tijuana, B.C. C.P.<br>22425 Mexico | 58865     | Ila           | 7       |
| 6.  | 21-2472-24     | SET, INTRO, 10Fr             | Smiths Healthcare Manufacturing S.A.<br>de C.V.<br>Avenida Calidad No. 4, Industrial<br>Internacional Tijuana, Tijuana, B.C. C.P.<br>22425 Mexico | 58865     | Ila           | 7       |
| 7.  | 21-2476-24     | SET, INTRO, 6Fr, VALVED      | Smiths Healthcare Manufacturing S.A.<br>de C.V.<br>Avenida Calidad No. 4, Industrial<br>Internacional Tijuana, Tijuana, B.C. C.P.<br>22425 Mexico | 58865     | Ila           | 7       |



**Declaration of Conformity**

S1144: Port-A-Cath Accessories

DoC-115  
Revision Number: 105

| 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.<br>de C.V.<br>Avenida Calidad No. 4, Industrial<br>Internacional Tijuana, Tijuana, B.C. C.P.<br>22425 Mexico | 58865     | Ila           | 7       |
| 9.  | 21-2478-24     | SET, INTRO 8.5Fr, VALVED         | Smiths Healthcare Manufacturing S.A.<br>de C.V.<br>Avenida Calidad No. 4, Industrial<br>Internacional Tijuana, Tijuana, B.C. C.P.<br>22425 Mexico | 58865     | Ila           | 7       |
| 10. | 21-2479-24     | SET, INTRO 9 Fr, VALVED          | Smiths Healthcare Manufacturing S.A.<br>de C.V.<br>Avenida Calidad No. 4, Industrial<br>Internacional Tijuana, Tijuana, B.C. C.P.<br>22425 Mexico | 58865     | Ila           | 7       |
| 11. | 21-2480-24     | SET, INTRO 10Fr, VALVED          | Smiths Healthcare Manufacturing S.A.<br>de C.V.<br>Avenida Calidad No. 4, Industrial<br>Internacional Tijuana, Tijuana, B.C. C.P.<br>22425 Mexico | 58865     | Ila           | 7       |
| 12. | 21-2481-24     | SET, INTRO 11Fr, VALVED          | Smiths Healthcare Manufacturing S.A.<br>de C.V.<br>Avenida Calidad No. 4, Industrial<br>Internacional Tijuana, Tijuana, B.C. C.P.<br>22425 Mexico | 58865     | Ila           | 7       |
| 13. | 21-2714-24     | NDL, GRIPPER, 22G X 1" (25MM)    | Smiths Healthcare Manufacturing S.A.<br>de C.V.<br>Avenida Calidad No. 4, Industrial<br>Internacional Tijuana, Tijuana, B.C. C.P.<br>22425 Mexico | 17701     | Ila           | 7       |
| 14. | 21-2715-24     | NDL, GRIPPER, 22G X 1.25" (32MM) | Smiths Healthcare Manufacturing S.A.<br>de C.V.<br>Avenida Calidad No. 4, Industrial<br>Internacional Tijuana, Tijuana, B.C. C.P.<br>22425 Mexico | 17701     | Ila           | 7       |



**Declaration of Conformity**

S1144: Port-A-Cath Accessories

DoC-115  
Revision Number: 105

| 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.<br>de C.V.<br>Avenida Calidad No. 4, Industrial<br>Internacional Tijuana, Tijuana, B.C. C.P.<br>22425 Mexico | 17701     | Ila           | 7       |
| 16. | 21-2718-24     | NDL, GRIPPER, 20G X 1.25" (32MM) | Smiths Healthcare Manufacturing S.A.<br>de C.V.<br>Avenida Calidad No. 4, Industrial<br>Internacional Tijuana, Tijuana, B.C. C.P.<br>22425 Mexico | 17701     | Ila           | 7       |
| 17. | 21-2720-24     | NDL, GRIPPER, 19G X 1" (25MM)    | Smiths Healthcare Manufacturing S.A.<br>de C.V.<br>Avenida Calidad No. 4, Industrial<br>Internacional Tijuana, Tijuana, B.C. C.P.<br>22425 Mexico | 17701     | Ila           | 7       |
| 18. | 21-2721-24     | NDL, GRIPPER, 19G X 1.25" (32MM) | Smiths Healthcare Manufacturing S.A.<br>de C.V.<br>Avenida Calidad No. 4, Industrial<br>Internacional Tijuana, Tijuana, B.C. C.P.<br>22425 Mexico | 17701     | Ila           | 7       |
| 19. | 21-2733-24     | NDL, GRIPPER, 22G X .75" (19MM)  | Smiths Healthcare Manufacturing S.A.<br>de C.V.<br>Avenida Calidad No. 4, Industrial<br>Internacional Tijuana, Tijuana, B.C. C.P.<br>22425 Mexico | 17701     | Ila           | 7       |
| 20. | 21-2734-24     | NDL, GRIPPER, 20G X .75" (19MM)  | Smiths Healthcare Manufacturing S.A.<br>de C.V.<br>Avenida Calidad No. 4, Industrial<br>Internacional Tijuana, Tijuana, B.C. C.P.<br>22425 Mexico | 17701     | Ila           | 7       |
| 21. | 21-2735-24     | NDL, GRIPPER, 19G X .75" (19MM)  | Smiths Healthcare Manufacturing S.A.<br>de C.V.<br>Avenida Calidad No. 4, Industrial<br>Internacional Tijuana, Tijuana, B.C. C.P.<br>22425 Mexico | 17701     | Ila           | 7       |



**Declaration of Conformity**

S1144: Port-A-Cath Accessories

DoC-115  
Revision Number: 105

| 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.<br>de C.V.<br>Avenida Calidad No. 4, Industrial<br>Internacional Tijuana, Tijuana, B.C. C.P.<br>22425 Mexico | 17701     | Ila           | 7       |
| 23. | 21-2737-24     | NDL, GRIPPER, 22G X .625" (16MM)      | Smiths Healthcare Manufacturing S.A.<br>de C.V.<br>Avenida Calidad No. 4, Industrial<br>Internacional Tijuana, Tijuana, B.C. C.P.<br>22425 Mexico | 17701     | Ila           | 7       |
| 24. | 21-2760-24     | NDL, GRIPPER PLUS, 22G X 1" (25MM)    | Smiths Healthcare Manufacturing S.A.<br>de C.V.<br>Avenida Calidad No. 4, Industrial<br>Internacional Tijuana, Tijuana, B.C. C.P.<br>22425 Mexico | 17701     | Ila           | 7       |
| 25. | 21-2761-24     | NDL, GRIPPER PLUS, 22G X 1.25" (32MM) | Smiths Healthcare Manufacturing S.A.<br>de C.V.<br>Avenida Calidad No. 4, Industrial<br>Internacional Tijuana, Tijuana, B.C. C.P.<br>22425 Mexico | 17701     | Ila           | 7       |
| 26. | 21-2762-24     | NDL, GRIPPER PLUS, 20G X 1" (25MM)    | Smiths Healthcare Manufacturing S.A.<br>de C.V.<br>Avenida Calidad No. 4, Industrial<br>Internacional Tijuana, Tijuana, B.C. C.P.<br>22425 Mexico | 17701     | Ila           | 7       |
| 27. | 21-2763-24     | NDL, GRIPPER PLUS, 20G X 1.25" (32MM) | Smiths Healthcare Manufacturing S.A.<br>de C.V.<br>Avenida Calidad No. 4, Industrial<br>Internacional Tijuana, Tijuana, B.C. C.P.<br>22425 Mexico | 17701     | Ila           | 7       |
| 28. | 21-2764-24     | NDL, GRIPPER PLUS, 19G X 1" (25MM)    | Smiths Healthcare Manufacturing S.A.<br>de C.V.<br>Avenida Calidad No. 4, Industrial<br>Internacional Tijuana, Tijuana, B.C. C.P.<br>22425 Mexico | 17701     | Ila           | 7       |



**Declaration of Conformity**

S1144: Port-A-Cath Accessories

DoC-115  
Revision Number: 105

| 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.<br>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.<br>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.<br>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.<br>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.<br>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.<br>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.<br>Avenida Calidad No. 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico | 17701     | Ila           | 7       |



**Declaration of Conformity**

S1144: Port-A-Cath Accessories

DoC-115  
Revision Number: 105

| 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.<br>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.<br>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.<br>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.<br>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.<br>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.<br>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.<br>Avenida Calidad No. 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico | 17701     | Ila           | 7       |



# Declaration of Conformity

S1144: Port-A-Cath Accessories

DoC-115  
Revision Number: 105

| 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.<br>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.<br>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.<br>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.<br>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.<br>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.<br>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.<br>Avenida Calidad No. 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico | 17701     | Ila           | 7       |



# Declaration of Conformity

S1144: Port-A-Cath Accessories

DoC-115  
Revision Number: 105

| 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.<br>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.<br>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.<br>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.<br>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.<br>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.<br>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.<br>Avenida Calidad No. 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico | 17701     | Ila           | 7       |



**Declaration of Conformity**

S1144: Port-A-Cath Accessories

DoC-115  
Revision Number: 105

| 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.<br>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.<br>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.<br>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.<br>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.<br>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.<br>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.<br>Avenida Calidad No. 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico | 17701     | Ila           | 7       |



**Declaration of Conformity**

S1144: Port-A-Cath Accessories

DoC-115  
Revision Number: 105

| 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.<br>Avenida Calidad No. 4, Industrial Internacional 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.<br>Avenida Calidad No. 4, Industrial Internacional 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.<br>Avenida Calidad No. 4, Industrial Internacional 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.<br>Avenida Calidad No. 4, Industrial Internacional 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.<br>Avenida Calidad No. 4, Industrial Internacional 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.<br>Avenida Calidad No. 4, Industrial Internacional 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.<br>Avenida Calidad No. 4, Industrial Internacional Tijuana, B.C. C.P. 22425 Mexico | 17701     | Ila           | 7       |



**Declaration of Conformity**

S1144: Port-A-Cath Accessories

DoC-115  
Revision Number: 105

| 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.<br>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.<br>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.<br>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.<br>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.<br>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.<br>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.<br>Avenida Calidad No. 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico | 17701     | Ila           | 7       |



# Declaration of Conformity

S1144: Port-A-Cath Accessories

DoC-115  
Revision Number: 105

| 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.<br>Avenida Calidad No. 4, Industrial Internacional 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.<br>Avenida Calidad No. 4, Industrial Internacional 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.<br>Avenida Calidad No. 4, Industrial Internacional 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.<br>Avenida Calidad No. 4, Industrial Internacional 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.<br>Avenida Calidad No. 4, Industrial Internacional 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.<br>Avenida Calidad No. 4, Industrial Internacional 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.<br>Avenida Calidad No. 4, Industrial Internacional Tijuana, B.C. C.P. 22425 Mexico | 17701     | Ila           | 7       |



**Declaration of Conformity**

S1144: Port-A-Cath Accessories

DoC-115  
Revision Number: 105

| 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.<br>de C.V.<br>Avenida Calidad No. 4, Industrial<br>Internacional Tijuana, Tijuana, B.C. C.P.<br>22425 Mexico | 17701     | Ila           | 7       |
| 86. | 21-3257-24     | NDL, GRIPPER MICRO, 20G X 1"                                        | Smiths Healthcare Manufacturing S.A.<br>de C.V.<br>Avenida Calidad No. 4, Industrial<br>Internacional Tijuana, Tijuana, B.C. C.P.<br>22425 Mexico | 17701     | Ila           | 7       |
| 87. | 21-3258-24     | NDL, GRIPPER MICRO, 20G X 1.25"                                     | Smiths Healthcare Manufacturing S.A.<br>de C.V.<br>Avenida Calidad No. 4, Industrial<br>Internacional Tijuana, Tijuana, B.C. C.P.<br>22425 Mexico | 17701     | Ila           | 7       |
| 88. | 21-3260-24     | NDL, GRIPPER MICRO, 19G X .75"                                      | Smiths Healthcare Manufacturing S.A.<br>de C.V.<br>Avenida Calidad No. 4, Industrial<br>Internacional Tijuana, Tijuana, B.C. C.P.<br>22425 Mexico | 17701     | Ila           | 7       |
| 89. | 21-3261-24     | NDL, GRIPPER MICRO, 19G X 1"                                        | Smiths Healthcare Manufacturing S.A.<br>de C.V.<br>Avenida Calidad No. 4, Industrial<br>Internacional Tijuana, Tijuana, B.C. C.P.<br>22425 Mexico | 17701     | Ila           | 7       |
| 90. | 21-3262-24     | NDL, GRIPPER MICRO, 19G X 1.25"                                     | Smiths Healthcare Manufacturing S.A.<br>de C.V.<br>Avenida Calidad No. 4, Industrial<br>Internacional Tijuana, Tijuana, B.C. C.P.<br>22425 Mexico | 17701     | Ila           | 7       |
| 91. | 21-3271-24     | NDL, GRIPPER MICRO, 22G X .75",<br>LUER ACTIVATED NEEDLELESS Y-SITE | Smiths Healthcare Manufacturing S.A.<br>de C.V.<br>Avenida Calidad No. 4, Industrial<br>Internacional Tijuana, Tijuana, B.C. C.P.<br>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.<br>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.<br>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.<br>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.<br>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.<br>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.<br>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.<br>Avenida Calidad No. 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico | 17701     | Ila           | 7       |



**Declaration of Conformity**

S1144: Port-A-Cath Accessories

DoC-115  
Revision Number: 105

| 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.<br>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.<br>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.<br>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.<br>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.<br>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.<br>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.<br>Avenida Calidad No. 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico | 17180     | Ila           | 7       |



**Declaration of Conformity**

S1144: Port-A-Cath Accessories

DoC-115  
Revision Number: 105

| 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.<br>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.<br>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.<br>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.<br>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.<br>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.<br>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.<br>Avenida Calidad No. 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico | 17180     | Ila           | 7       |



**smiths medical**  
bringing technology to life

**Declaration of Conformity**

S1144: Port-A-Cath Accessories

DoC-115  
Revision Number: 105

| 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.),<br>90 DEG BENT | Smiths Healthcare Manufacturing S.A.<br>de C.V.<br>Avenida Calidad No. 4, Industrial<br>Internacional Tijuana, Tijuana, B.C. C.P.<br>22425 Mexico | 17180     | Ila           | 7       |
| 114. | 21-2317-24     | NDL, PH, 0.9MM (20G) X 13MM (1/2 IN.),<br>90 DEG BENT | Smiths Healthcare Manufacturing S.A.<br>de C.V.<br>Avenida Calidad No. 4, Industrial<br>Internacional Tijuana, Tijuana, B.C. C.P.<br>22425 Mexico | 17180     | Ila           | 7       |
| 115. | 21-0125-24     | SUBCUTANEOUS TUNNELING DEV                            | Smiths Healthcare Manufacturing S.A.<br>de C.V.<br>Avenida Calidad No. 4, Industrial<br>Internacional Tijuana, Tijuana, B.C. C.P.<br>22425 Mexico | 46801     | Ila           | 7       |