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

| | |
|---|---|
| **Legal Manufacturer:** | Smiths Medical ASD Inc.<br>6000 Nathan Lane North<br>Minneapolis, Minnesota 55442 USA |
| **EU Representative:** | Smiths Medical Czech Republic a. s.<br>Olomoucká 306,<br>Hranice 1 - Město,<br>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<br>Medical Devices Certification<br>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.<br>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.<br>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.<br>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.<br>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.<br>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.<br>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.<br>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.<br>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.<br>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.<br>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.<br>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.<br>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.<br>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.<br>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.<br>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.<br>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.<br>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.<br>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.<br>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.<br>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.<br>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<br>-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<br>-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.<br>-Added “Deltec®” as a tradename as the SKUs listed on this DoC are Deltec® Port-A-Cath.<br>-Updated the Product Descriptions of the Catalog Numbers in Appendix 1 to match their Descriptions in Agile<br>-Changed the Tijuana Manufacturing Site address to match EC Certificate 669121.<br>-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. | | |