| smiths medical<br>bringing technology to life | **Declaration of Conformity**<br>S1028: Intubation and Endotracheal Tubes | DoC-034<br>Revision Number: 110 |
|---|---|---|

| | |
|---|---|
| **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):** | Blue Line® tracheostomy tube, PROFILE™ tracheal tube, SOFT-SEAL® tracheostomy tubes, Polar endotracheal tubes, SACETT® tracheal tube, SidePort™ inflation line connector |
| **Product Scope:** | Sterile and non-sterile Applications for patient Intubation |
| **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 |
| **Start of CE-Marking:** | OCT, 1996 |

We hereby declare that the products listed in Appendix 1 conform with the relevant provisions of Directive 93/42/EEC of June 14, 1993 as transposed into UK law by Statutory Instrument S.I. 2008 No. 2936 and as amended by Directive 2007/47/EC of the European Parliament and of the Council of September 5, 2007 concerning medical devices as transposed into national regulations and by subsequent Directives, laws, and other national regulations. We are hereby exclusively responsible for the contents found on this declaration of conformity. All supporting documentation is retained under the premise of the Manufacturer.

**Authorized Signatory:**

Signature: Stacy Novak Date: 07AUG2019

Name: Stacy Novak

Title: Sr. Manager, Regulatory Operations

Location of Signatory: Minneapolis, MN, USA

**Appendix 1: Product List**

| Num | Catalog Number | Product Description | Manufacturing Site | UMDNS (if applicable) | GMDN Code | EU Risk Class | EU Rule |
|---|---|---|---|---|---|---|---|
| 1. | 100/105/025 | Tracheal Tube Ivory Uncuffed Oral/Nasal 2.5MM | Smiths Healthcare Manufacturing S.A. De C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico | N/A | 46967 | IIa | 5 |
| 2. | 100/105/030 | Tracheal Tube Ivory Uncuffed Oral/Nasal 3.0MM | Smiths Healthcare Manufacturing S.A. De C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico | N/A | 46967 | IIa | 5 |
| 3. | 100/105/035 | Tracheal Tube Ivory Uncuffed Oral/Nasal 3.5MM | Smiths Healthcare Manufacturing S.A. De C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico | N/A | 46967 | IIa | 5 |
| 4. | 100/105/040 | Tracheal Tube Ivory Uncuffed Oral/Nasal 4.0MM | Smiths Healthcare Manufacturing S.A. De C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico | N/A | 46967 | IIa | 5 |
| 5. | 100/105/045 | Tracheal Tube Ivory Uncuffed Oral/Nasal 4.5MM | Smiths Healthcare Manufacturing S.A. De C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico | N/A | 46967 | IIa | 5 |
| 6. | 100/105/050 | Tracheal Tube Ivory Uncuffed Oral/Nasal 5.0MM | Smiths Healthcare Manufacturing S.A. De C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico | N/A | 46967 | IIa | 5 |
| 7. | 100/105/055 | Tracheal Tube Ivory Uncuffed Oral/Nasal 5.5MM | Smiths Healthcare Manufacturing S.A. De C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico | N/A | 46967 | IIa | 5 |

| Num | Catalog Number | Product Description | Manufacturing Site | UMDNS (if applicable) | GMDN Code | EU Risk Class | EU Rule |
|---|---|---|---|---|---|---|---|
| 8. | 100/105/060 | Tracheal Tube Ivory Uncuffed Oral/Nasal 6.0MM | Smiths Healthcare Manufacturing S.A. De C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico | N/A | 46967 | IIa | 5 |
| 9. | 100/105/065 | Tracheal Tube Ivory Uncuffed Oral/Nasal 6.5MM | Smiths Healthcare Manufacturing S.A. De C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico | N/A | 46967 | IIa | 5 |
| 10. | 100/105/070 | Tracheal Tube Ivory Uncuffed Oral/Nasal 7.0MM | Smiths Healthcare Manufacturing S.A. De C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico | N/A | 46967 | IIa | 5 |
| 11. | 100/105/075 | Tracheal Tube Ivory Uncuffed Oral/Nasal 7.5MM | Smiths Healthcare Manufacturing S.A. De C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico | N/A | 46967 | IIa | 5 |
| 12. | 100/105/080 | Tracheal Tube Ivory Uncuffed Oral/Nasal 8.0MM | Smiths Healthcare Manufacturing S.A. De C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico | N/A | 46967 | IIa | 5 |
| 13. | 100/105/085 | Tracheal Tube Ivory Uncuffed Oral/Nasal 8.5MM | Smiths Healthcare Manufacturing S.A. De C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico | N/A | 46967 | IIa | 5 |
| 14. | 100/105/090 | Tracheal Tube Ivory Uncuffed Oral/Nasal 9.0MM | Smiths Healthcare Manufacturing S.A. De C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico | N/A | 46967 | IIa | 5 |

| Num | Catalog Number | Product Description | Manufacturing Site | UMDNS (if applicable) | GMDN Code | EU Risk Class | EU Rule |
|---|---|---|---|---|---|---|---|
| 15. | 100/107/030 | Tracheal Tube Reinforced 3.0mm Oral/Nasal Uncuffed Reusable | Smiths Healthcare Manufacturing SA de CV Carretera Miguel Aleman Km 21.7, Parque Industrial Monterrey, Apodaca NL CP 66603 Mexico | N/A | 47121 | IIa | 5 |
| 16. | 100/107/035 | Tracheal Tube Reinforced 3.5mm Oral/Nasal Uncuffed Reusable | Smiths Healthcare Manufacturing SA de CV Carretera Miguel Aleman Km 21.7, Parque Industrial Monterrey, Apodaca NL CP 66603 Mexico | N/A | 47121 | IIa | 5 |
| 17. | 100/107/040 | Tracheal Tube Reinforced 4.0mm Oral/Nasal Uncuffed Reusable | Smiths Healthcare Manufacturing SA de CV Carretera Miguel Aleman Km 21.7, Parque Industrial Monterrey, Apodaca NL CP 66603 Mexico | N/A | 47121 | IIa | 5 |
| 18. | 100/107/045 | Tracheal Tube Reinforced 4.5mm Oral/Nasal Uncuffed Reusable | Smiths Healthcare Manufacturing SA de CV Carretera Miguel Aleman Km 21.7, Parque Industrial Monterrey, Apodaca NL CP 66603 Mexico | N/A | 47121 | IIa | 5 |
| 19. | 100/107/050 | Tracheal Tube Reinforced 5.0mm Oral/Nasal Uncuffed Reusable | Smiths Healthcare Manufacturing SA de CV Carretera Miguel Aleman Km 21.7, Parque Industrial Monterrey, Apodaca NL CP 66603 Mexico | N/A | 47121 | IIa | 5 |
| 20. | 100/109/055 | Tracheal Reinforced 5.5mm Oral/Nasal Trad. Cuff M/Eye | Smiths Healthcare Manufacturing SA de CV Carretera Miguel Aleman Km 21.7, Parque Industrial Monterrey, Apodaca NL CP 66603 Mexico | N/A | 47121 | IIa | 5 |

| Num | Catalog Number | Product Description | Manufacturing Site | UMDNS (if applicable) | GMDN Code | EU Risk Class | EU Rule |
|---|---|---|---|---|---|---|---|
| 21. | 100/109/060 | Tracheal Tube Reinforced 6.0mmoral/Nasal Cuff M/Eye Reusable | Smiths Healthcare Manufacturing SA de CV Carretera Miguel Aleman Km 21.7, Parque Industrial Monterrey, Apodaca NL CP 66603 Mexico | N/A | 47121 | IIa | 5 |
| 22. | 100/109/065 | Tracheal Reinforced 6.5mm Oral/Nasal, Trad. Cuff, M/Eye | Smiths Healthcare Manufacturing SA de CV Carretera Miguel Aleman Km 21.7, Parque Industrial Monterrey, Apodaca NL CP 66603 Mexico | N/A | 47121 | IIa | 5 |
| 23. | 100/109/070 | Tracheal Tube Reinforced 7.0mmoral/Nasal Cuff M/Eye Reusable | Smiths Healthcare Manufacturing SA de CV Carretera Miguel Aleman Km 21.7, Parque Industrial Monterrey, Apodaca NL CP 66603 Mexico | N/A | 47121 | IIa | 5 |
| 24. | 100/109/075 | Tracheal Reinforced 7.5mm Oral/Nasal, Trad. Cuff, M/Eye | Smiths Healthcare Manufacturing SA de CV Carretera Miguel Aleman Km 21.7, Parque Industrial Monterrey, Apodaca NL CP 66603 Mexico | N/A | 47121 | IIa | 5 |
| 25. | 100/109/080 | Tracheal Tube Reinforced 8.0mmoral/Nasal Cuff M/Eye Reusable | Smiths Healthcare Manufacturing SA de CV Carretera Miguel Aleman Km 21.7, Parque Industrial Monterrey, Apodaca NL CP 66603 Mexico | N/A | 47121 | IIa | 5 |
| 26. | 100/109/085 | Tracheal Reinforced 8.5mm Oral/Nasal, Trad. Cuff, M/Eye | Smiths Healthcare Manufacturing SA de CV Carretera Miguel Aleman Km 21.7, Parque Industrial Monterrey, Apodaca NL CP 66603 Mexico | N/A | 47121 | IIa | 5 |

| Num | Catalog Number | Product Description | Manufacturing Site | UMDNS (if applicable) | GMDN Code | EU Risk Class | EU Rule |
|---|---|---|---|---|---|---|---|
| 27. | 100/109/090 | Tracheal Tube Reinforced 9.0mm Oral/Nasal Cuff M/Eye Reusable | Smiths Healthcare Manufacturing SA de CV Carretera Miguel Aleman Km 21.7, Parque Industrial Monterrey, Apodaca NL CP 66603 Mexico | N/A | 47121 | IIa | 5 |
| 28. | 100/110/050 | Reinforced Tracheal Cuffed 5.0mm Single Use | Smiths Healthcare Manufacturing S.A. De C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico | N/A | 46569 | IIa | 5 |
| 29. | 100/110/055 | Reinforced Tracheal Cuffed 5.5mm Single Use | Smiths Healthcare Manufacturing S.A. De C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico | N/A | 46569 | IIa | 5 |
| 30. | 100/110/060 | Reinforced Tracheal Cuffed 6.0mm Single Use | Smiths Healthcare Manufacturing S.A. De C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico | N/A | 46569 | IIa | 5 |
| 31. | 100/110/065 | Reinforced Tracheal Cuffed 6.5mm Single Use | Smiths Healthcare Manufacturing S.A. De C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico | N/A | 46569 | IIa | 5 |
| 32. | 100/110/070 | Reinforced Tracheal Cuffed 7.0mm Single Use | Smiths Healthcare Manufacturing S.A. De C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico | N/A | 46569 | IIa | 5 |
| 33. | 100/110/075 | Reinforced Tracheal Cuffed 7.5mm Single Use | Smiths Healthcare Manufacturing S.A. De C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico | N/A | 46569 | IIa | 5 |

| Num | Catalog Number | Product Description | Manufacturing Site | UMDNS (if applicable) | GMDN Code | EU Risk Class | EU Rule |
|---|---|---|---|---|---|---|---|
| 34. | 100/110/080 | Reinforced Tracheal Cuffed 8.0mm Single Use | Smiths Healthcare Manufacturing S.A. De C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico | N/A | 46569 | IIa | 5 |
| 35. | 100/110/085 | Reinforced Tracheal Cuffed 8.5mm Single Use | Smiths Healthcare Manufacturing S.A. De C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico | N/A | 46569 | IIa | 5 |
| 36. | 100/110/090 | Reinforced Tracheal Cuffed 9.0mm Single Use | Smiths Healthcare Manufacturing S.A. De C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico | N/A | 46569 | IIa | 5 |
| 37. | 100/110/095 | Reinforced Tracheal Cuffed 9.5mm Single Use | Smiths Healthcare Manufacturing S.A. De C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico | N/A | 46569 | IIa | 5 |
| 38. | 100/111/020 | Tracheal Tube Siliconised Oral/Nasal Uncuffed 2.0mm | Smiths Healthcare Manufacturing S.A. De C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico | N/A | 46967 | IIa | 5 |
| 39. | 100/111/025 | Tracheal Tube Siliconised Oral/Nasal Uncuffed 2.5mm | Smiths Healthcare Manufacturing S.A. De C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico | N/A | 46967 | IIa | 5 |
| 40. | 100/111/030 | Tracheal Tube Siliconised Oral/Nasal Uncuffed 3.0mm | Smiths Healthcare Manufacturing S.A. De C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico | N/A | 46967 | IIa | 5 |

| Num | Catalog Number | Product Description | Manufacturing Site | UMDNS (if applicable) | GMDN Code | EU Risk Class | EU Rule |
|---|---|---|---|---|---|---|---|
| 41. | 100/111/035 | Tracheal Tube Siliconised Oral/Nasal Uncuffed 3.5mm | Smiths Healthcare Manufacturing S.A. De C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico | N/A | 46967 | IIa | 5 |
| 42. | 100/111/040 | Tracheal Tube Siliconised Oral/Nasal Uncuffed 4.0mm | Smiths Healthcare Manufacturing S.A. De C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico | N/A | 46967 | IIa | 5 |
| 43. | 100/111/045 | Tracheal Tube Siliconised Oral/Nasal Uncuffed 4.5mm | Smiths Healthcare Manufacturing S.A. De C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico | N/A | 46967 | IIa | 5 |
| 44. | 100/111/050 | Tracheal Tube Siliconised Oral/Nasal Uncuffed 5.0mm | Smiths Healthcare Manufacturing S.A. De C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico | N/A | 46967 | IIa | 5 |
| 45. | 100/111/055 | Tracheal Tube Siliconised Oral/Nasal Uncuffed 5.5mm | Smiths Healthcare Manufacturing S.A. De C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico | N/A | 46967 | IIa | 5 |
| 46. | 100/111/060 | Tracheal Tube Siliconised Oral/Nasal Uncuffed 6.0mm | Smiths Healthcare Manufacturing S.A. De C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico | N/A | 46967 | IIa | 5 |
| 47. | 100/111/065 | Tracheal Tube Siliconised Oral/Nasal Uncuffed 6.5mm | Smiths Healthcare Manufacturing S.A. De C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico | N/A | 46967 | IIa | 5 |

| Num | Catalog Number | Product Description | Manufacturing Site | UMDNS (if applicable) | GMDN Code | EU Risk Class | EU Rule |
|---|---|---|---|---|---|---|---|
| 48. | 100/111/070 | Tracheal Tube Siliconised Oral/Nasal Uncuffed 7.0mm | Smiths Healthcare Manufacturing S.A. De C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico | N/A | 46967 | IIa | 5 |
| 49. | 100/111/075 | Tracheal Tube Siliconised Oral/Nasal Uncuffed 7.5mm | Smiths Healthcare Manufacturing S.A. De C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico | N/A | 46967 | IIa | 5 |
| 50. | 100/111/080 | Tracheal Tube Siliconised Oral/Nasal Uncuffed 8.0mm | Smiths Healthcare Manufacturing S.A. De C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico | N/A | 46967 | IIa | 5 |
| 51. | 100/111/085 | Tracheal Tube Siliconised Oral/Nasal Uncuffed 8.5mm | Smiths Healthcare Manufacturing S.A. De C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico | N/A | 46967 | IIa | 5 |
| 52. | 100/111/090 | Tracheal Tube Siliconised Oral/Nasal Uncuffed 9.0mm | Smiths Healthcare Manufacturing S.A. De C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico | N/A | 46967 | IIa | 5 |
| 53. | 100/112/025 | Tracheal Tube Paed Croup Extra Long Oral/Nasal Uncuffed 2.5mm | Smiths Healthcare Manufacturing S.A. De C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico | N/A | 46967 | IIa | 5 |
| 54. | 100/112/030 | Tracheal Tube Paed Croup Extra Long Oral/Nasal Uncuffed 3.0mm | Smiths Healthcare Manufacturing S.A. De C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico | N/A | 46967 | IIa | 5 |

| Num | Catalog Number | Product Description | Manufacturing Site | UMDNS (if applicable) | GMDN Code | EU Risk Class | EU Rule |
|---|---|---|---|---|---|---|---|
| 55. | 100/112/045 | Tracheal Tube Paed Croup Extra Long Oral/Nasal Uncuffed 4.5mm | Smiths Healthcare Manufacturing S.A. De C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico | N/A | 46967 | IIa | 5 |
| 56. | 100/113/030 | Reinforced Tracheal Uncuffed 3.0mm Single Use | Smiths Healthcare Manufacturing S.A. De C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico | N/A | 46569 | IIa | 5 |
| 57. | 100/113/035 | Reinforced Tracheal Uncuffed 3.5mm Single Use | Smiths Healthcare Manufacturing S.A. De C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico | N/A | 46569 | IIa | 5 |
| 58. | 100/113/040 | Reinforced Tracheal Uncuffed 4.0mm Single Use | Smiths Healthcare Manufacturing S.A. De C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico | N/A | 46569 | IIa | 5 |
| 59. | 100/113/045 | Reinforced Tracheal Uncuffed 4.5mm Single Use | Smiths Healthcare Manufacturing S.A. De C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico | N/A | 46569 | IIa | 5 |
| 60. | 100/113/050 | Reinforced Tracheal Uncuffed 5.0mm Single Use | Smiths Healthcare Manufacturing S.A. De C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico | N/A | 46569 | IIa | 5 |
| 61. | 100/126/025 | Tracheal Tube, Siliconized Cut-To-Length,Oral 2.5mm | Smiths Healthcare Manufacturing S.A. De C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico | N/A | 46967 | IIa | 5 |

| Num | Catalog Number | Product Description | Manufacturing Site | UMDNS (if applicable) | GMDN Code | EU Risk Class | EU Rule |
|---|---|---|---|---|---|---|---|
| 62. | 100/126/030 | Tracheal Tube, Siliconized Cut-To-Length,Oral 3.0mm | Smiths Healthcare Manufacturing S.A. De C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico | N/A | 46967 | IIa | 5 |
| 63. | 100/126/035 | Tracheal Tube,Siliconized Cut-To-Length,Oral 3.5mm | Smiths Healthcare Manufacturing S.A. De C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico | N/A | 46967 | IIa | 5 |
| 64. | 100/126/040 | Tracheal Tube,Siliconized Cut-To-Length,Oral 4.0mm | Smiths Healthcare Manufacturing S.A. De C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico | N/A | 46967 | IIa | 5 |
| 65. | 100/126/045 | Tracheal Tube, Siliconized Cut-To-Length, Oral 4.5mm | Smiths Healthcare Manufacturing S.A. De C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico | N/A | 46967 | IIa | 5 |
| 66. | 100/126/050 | Tracheal Tube, Siliconized Cut-To-Length, Oral 5.0mm | Smiths Healthcare Manufacturing S.A. De C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico | N/A | 46967 | IIa | 5 |
| 67. | 100/126/055 | Tracheal Tube, Siliconized Cut-To-Length, Oral 5.5mm | Smiths Healthcare Manufacturing S.A. De C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico | N/A | 46967 | IIa | 5 |
| 68. | 100/126/060 | Tracheal Tube, Siliconized Cut-To-Length, Oral 6.0mm | Smiths Healthcare Manufacturing S.A. De C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico | N/A | 46967 | IIa | 5 |

| Num | Catalog Number | Product Description | Manufacturing Site | UMDNS (if applicable) | GMDN Code | EU Risk Class | EU Rule |
|---|---|---|---|---|---|---|---|
| 69. | 100/127/025 | Tracheal Tube, Uncuffed 2.5mm Murphy Eye Oral/Nasal | Smiths Healthcare Manufacturing S.A. De C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico | N/A | 46967 | IIa | 5 |
| 70. | 100/127/030 | Tracheal Tube, Uncuffed 3.0mm Murphy Eye Oral/Nasal | Smiths Healthcare Manufacturing S.A. De C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico | N/A | 46967 | IIa | 5 |
| 71. | 100/127/035 | Tracheal Tube, Uncuffed 3.5mm Murphy Eye Oral/Nasal | Smiths Healthcare Manufacturing S.A. De C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico | N/A | 46967 | IIa | 5 |
| 72. | 100/127/040 | Tracheal Tube, Uncuffed 4.0mm Murphy Eye Oral/Nasal | Smiths Healthcare Manufacturing S.A. De C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico | N/A | 46967 | IIa | 5 |
| 73. | 100/127/045 | Tracheal Tube, Uncuffed 4.5mm Murphy Eye Oral/Nasal | Smiths Healthcare Manufacturing S.A. De C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico | N/A | 46967 | IIa | 5 |
| 74. | 100/127/050 | Tracheal Tube, Uncuffed 5.0mm Murphy Eye Oral/Nasal | Smiths Healthcare Manufacturing S.A. De C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico | N/A | 46967 | IIa | 5 |
| 75. | 100/127/055 | Tracheal Tube, Uncuffed 5.5mm Murphy Eye Oral/Nasal | Smiths Healthcare Manufacturing S.A. De C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico | N/A | 46967 | IIa | 5 |

| Num | Catalog Number | Product Description | Manufacturing Site | UMDNS (if applicable) | GMDN Code | EU Risk Class | EU Rule |
|---|---|---|---|---|---|---|---|
| 76. | 100/127/060 | Tracheal Tube, Uncuffed 6.0mm Murphy Eye Oral/Nasal | Smiths Healthcare Manufacturing S.A. De C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico | N/A | 46967 | IIa | 5 |
| 77. | 100/127/065 | Tracheal Tube, Uncuffed 6.5mm Murphy Eye Oral/Nasal | Smiths Healthcare Manufacturing S.A. De C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico | N/A | 46967 | IIa | 5 |
| 78. | 100/127/070 | Tracheal Tube, Uncuffed 7.0mm Murphy Eye Oral/Nasal | Smiths Healthcare Manufacturing S.A. De C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico | N/A | 46967 | IIa | 5 |
| 79. | 100/127/075 | Tracheal Tube, Uncuffed 7.5mm Murphy Eye Oral/Nasal | Smiths Healthcare Manufacturing S.A. De C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico | N/A | 46967 | IIa | 5 |
| 80. | 100/127/080 | Tracheal Tube, Uncuffed 8.0mm Murphy Eye Oral/Nasal | Smiths Healthcare Manufacturing S.A. De C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico | N/A | 46967 | IIa | 5 |
| 81. | 100/127/085 | Tracheal Tube, Uncuffed 8.5mm Murphy Eye Oral/Nasal | Smiths Healthcare Manufacturing S.A. De C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico | N/A | 46967 | IIa | 5 |
| 82. | 100/127/090 | Tracheal Tube, Uncuffed 9.0mm Murphy Eye Oral/Nasal | Smiths Healthcare Manufacturing S.A. De C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico | N/A | 46967 | IIa | 5 |

| Num | Catalog Number | Product Description | Manufacturing Site | UMDNS (if applicable) | GMDN Code | EU Risk Class | EU Rule |
|---|---|---|---|---|---|---|---|
| 83. | 100/127/095 | Tracheal Tube, Uncuffed 9.5mm Murphy Eye Oral/Nasal | Smiths Healthcare Manufacturing S.A. De C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico | N/A | 46967 | IIa | 5 |
| 84. | 100/127/100 | Tracheal Tube, Uncuffed 10.0mm Murphy Eye Oral/Nasal | Smiths Healthcare Manufacturing S.A. De C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico | N/A | 46967 | IIa | 5 |
| 85. | 100/130/060 | Tracheal Tube Polar Uncuffed North Nasal Polyurethane 6.0mm | Smiths Healthcare Manufacturing S.A. De C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico | N/A | 46967 | IIa | 5 |
| 86. | 100/130/065 | Tracheal Tube Polar Uncuffed North Nasal Polyurethane 6.5mm | Smiths Healthcare Manufacturing S.A. De C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico | N/A | 46967 | IIa | 5 |
| 87. | 100/130/070 | Tracheal Tube Polar Uncuffed North Nasal Polyurethane 7.0mm | Smiths Healthcare Manufacturing S.A. De C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico | N/A | 46967 | IIa | 5 |
| 88. | 100/130/075 | Tracheal Tube Polar Uncuffed North Nasal Polyurethane 7.5mm | Smiths Healthcare Manufacturing S.A. De C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico | N/A | 46967 | IIa | 5 |
| 89. | 100/130/080 | Tracheal Tube Polar Uncuffed North Nasal Polyurethane 8.0mm | Smiths Healthcare Manufacturing S.A. De C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico | N/A | 46967 | IIa | 5 |

| Num | Catalog Number | Product Description | Manufacturing Site | UMDNS (if applicable) | GMDN Code | EU Risk Class | EU Rule |
|---|---|---|---|---|---|---|---|
| 90. | 100/131/060 | Polar Tracheal Tube North Oralprof Cuff Clear M/Eye 6.0mm | Smiths Healthcare Manufacturing S.A. De C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico | N/A | 46967 | IIa | 5 |
| 91. | 100/131/065 | Polar Tracheal Tube North Oralprof Cuff Clear M/Eye 6.5mm | Smiths Healthcare Manufacturing S.A. De C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico | N/A | 46967 | IIa | 5 |
| 92. | 100/131/070 | Polar Tracheal Tube North Oralprof Cuff Clear M/Eye 7.0mm | Smiths Healthcare Manufacturing S.A. De C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico | N/A | 46967 | IIa | 5 |
| 93. | 100/131/075 | Polar Tracheal Tube North Oralprof Cuff Clear M/Eye 7.5mm | Smiths Healthcare Manufacturing S.A. De C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico | N/A | 46967 | IIa | 5 |
| 94. | 100/131/080 | Polar Tracheal Tube North Oralprof Cuff Clear M/Eye 8.0mm | Smiths Healthcare Manufacturing S.A. De C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico | N/A | 46967 | IIa | 5 |
| 95. | 100/131/085 | Polar Tracheal Tube North Oral Prof Cuff Clear M/Eye 8.5mm | Smiths Healthcare Manufacturing S.A. De C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico | N/A | 46967 | IIa | 5 |
| 96. | 100/131/090 | Polar Tracheal Tube North Oral Prof Cuff Clear M/Eye 9.0mm | Smiths Healthcare Manufacturing S.A. De C.V. Avenida Calidad No 4, Parque Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico | N/A | 46967 | IIa | 5 |

| Num | Catalog Number | Product Description | Manufacturing Site | UMDNS (if applicable) | GMDN Code | EU Risk Class | EU Rule |
|---|---|---|---|---|---|---|---|
| 97. | 100/132/030 | Tracheal Tube Polar Clear North Oral Uncuffed 3.0mm | Smiths Healthcare Manufacturing S.A. De C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico | N/A | 46967 | IIa | 5 |
| 98. | 100/132/035 | Tracheal Tube Polar Clear North Oral Uncuffed 3.5mm | Smiths Healthcare Manufacturing S.A. De C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico | N/A | 46967 | IIa | 5 |
| 99. | 100/132/040 | Tracheal Tube Polar Clear North Oral Uncuffed 4.0mm | Smiths Healthcare Manufacturing S.A. De C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico | N/A | 46967 | IIa | 5 |
| 100. | 100/132/045 | Tracheal Tube Polar Clear North Oral Uncuffed 4.5mm | Smiths Healthcare Manufacturing S.A. De C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico | N/A | 46967 | IIa | 5 |
| 101. | 100/132/050 | Tracheal Tube Polar Clear North Oral Uncuffed 5.0mm | Smiths Healthcare Manufacturing S.A. De C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico | N/A | 46967 | IIa | 5 |
| 102. | 100/132/055 | Tracheal Tube Polar Clear North Oral Uncuffed 5.5mm | Smiths Healthcare Manufacturing S.A. De C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico | N/A | 46967 | IIa | 5 |
| 103. | 100/132/060 | Tracheal Tube Polar Clear North Oral Uncuffed 6.0mm | Smiths Healthcare Manufacturing S.A. De C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico | N/A | 46967 | IIa | 5 |

| Num | Catalog Number | Product Description | Manufacturing Site | UMDNS (if applicable) | GMDN Code | EU Risk Class | EU Rule |
|---|---|---|---|---|---|---|---|
| 104. | 100/132/065 | Tracheal Tube Polar Clear North Oral Uncuffed 6.5mm | Smiths Healthcare Manufacturing S.A. De C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico | N/A | 46967 | IIa | 5 |
| 105. | 100/132/070 | Tracheal Tube Polar Clear North Oral Uncuffed 7.0mm | Smiths Healthcare Manufacturing S.A. De C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico | N/A | 46967 | IIa | 5 |
| 106. | 100/133/060 | Tracheal Tube Maxillo Facial N/Nasal Ivory S/Sl Cuff 6.0mm | Smiths Healthcare Manufacturing S.A. De C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico | N/A | 46967 | IIa | 5 |
| 107. | 100/133/065 | Tracheal Tube Maxillo Facial N/Nasal Ivory S/Sl Cuff 6.5mm | Smiths Healthcare Manufacturing S.A. De C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico | N/A | 46967 | IIa | 5 |
| 108. | 100/133/070 | Tracheal Tube Maxillo Facial N/Nasal Ivory S/Sl Cuff 7.0mm | Smiths Healthcare Manufacturing S.A. De C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico | N/A | 46967 | IIa | 5 |
| 109. | 100/133/075 | Tracheal Tube Maxillo Facial N/Nasal Ivory S/Sl Cuff 7.5mm | Smiths Healthcare Manufacturing S.A. De C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico | N/A | 46967 | IIa | 5 |
| 110. | 100/133/080 | Tracheal Tube Maxillo Facial N/Nasal Ivory S/Sl Cuff 8.0mm | Smiths Healthcare Manufacturing S.A. De C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico | N/A | 46967 | IIa | 5 |

| Num | Catalog Number | Product Description | Manufacturing Site | UMDNS (if applicable) | GMDN Code | EU Risk Class | EU Rule |
|---|---|---|---|---|---|---|---|
| 111. | 100/134/030 | Tracheal Tube Polar Clear South Oral Uncuffed 3.0mm | Smiths Healthcare Manufacturing S.A. De C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico | N/A | 46967 | IIa | 5 |
| 112. | 100/134/035 | Tracheal Tube Polar Clear South Oral Uncuffed 3.5mm | Smiths Healthcare Manufacturing S.A. De C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico | N/A | 46967 | IIa | 5 |
| 113. | 100/134/040 | Tracheal Tube Polar Clear South Oral Uncuffed 4.0mm | Smiths Healthcare Manufacturing S.A. De C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico | N/A | 46967 | IIa | 5 |
| 114. | 100/134/045 | Tracheal Tube Polar Clear South Oral Uncuffed 4.5mm | Smiths Healthcare Manufacturing S.A. De C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico | N/A | 46967 | IIa | 5 |
| 115. | 100/134/050 | Tracheal Tube Polar Clear South Oral Uncuffed 5.0mm | Smiths Healthcare Manufacturing S.A. De C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico | N/A | 46967 | IIa | 5 |
| 116. | 100/134/055 | Tracheal Tube Polar Clear South Oral Uncuffed 5.5mm | Smiths Healthcare Manufacturing S.A. De C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico | N/A | 46967 | IIa | 5 |
| 117. | 100/134/060 | Tracheal Tube Polar Clear South Oral Uncuffed 6.0mm | Smiths Healthcare Manufacturing S.A. De C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico | N/A | 46967 | IIa | 5 |

| Num | Catalog Number | Product Description | Manufacturing Site | UMDNS (if applicable) | GMDN Code | EU Risk Class | EU Rule |
|---|---|---|---|---|---|---|---|
| 118. | 100/134/065 | Tracheal Tube Polar Clear South Oral Uncuffed 6.5mm | Smiths Healthcare Manufacturing S.A. De C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico | N/A | 46967 | IIa | 5 |
| 119. | 100/134/070 | Tracheal Tube Polar Clear South Oral Uncuffed 7.0mm | Smiths Healthcare Manufacturing S.A. De C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico | N/A | 46967 | IIa | 5 |
| 120. | 100/134/075 | Tracheal Tube Polar Clear South Oral Uncuffed 7.5mm | Smiths Healthcare Manufacturing S.A. De C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico | N/A | 46967 | IIa | 5 |
| 121. | 100/136/050 | Tracheal Tube Polar Clear Sth Oral Soft Seal Cuff 5.0mm | Smiths Healthcare Manufacturing S.A. De C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico | N/A | 46967 | IIa | 5 |
| 122. | 100/136/055 | Tracheal Tube Polar Clear Sth Oral Soft Seal Cuff 5.5mm | Smiths Healthcare Manufacturing S.A. De C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico | N/A | 46967 | IIa | 5 |
| 123. | 100/136/060 | Tracheal Tube Polar Clear Sth Oral Soft Seal Cuff 6.0mm | Smiths Healthcare Manufacturing S.A. De C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico | N/A | 46967 | IIa | 5 |
| 124. | 100/136/065 | Tracheal Tube Polar Clear Sth Oral Soft Seal Cuff 6.5mm | Smiths Healthcare Manufacturing S.A. De C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico | N/A | 46967 | IIa | 5 |

| Num | Catalog Number | Product Description | Manufacturing Site | UMDNS (if applicable) | GMDN Code | EU Risk Class | EU Rule |
|---|---|---|---|---|---|---|---|
| 125. | 100/136/070 | Tracheal Tube Polar Clear Sth Oral Soft Seal Cuff 7.0mm | Smiths Healthcare Manufacturing S.A. De C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico | N/A | 46967 | IIa | 5 |
| 126. | 100/136/075 | Tracheal Tube Polar Clear Sth Oral Soft Seal Cuff 7.5mm | Smiths Healthcare Manufacturing S.A. De C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico | N/A | 46967 | IIa | 5 |
| 127. | 100/136/080 | Tracheal Tube Polar Clear Sth Oral Soft Seal Cuff 8.0mm | Smiths Healthcare Manufacturing S.A. De C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico | N/A | 46967 | IIa | 5 |
| 128. | 100/136/085 | Tracheal Tube Polar Clear Sth Oral Soft Seal Cuff 8.5mm | Smiths Healthcare Manufacturing S.A. De C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico | N/A | 46967 | IIa | 5 |
| 129. | 100/136/090 | Tracheal Tube Polar Clear Sth Oral Soft Seal Cuff 9.0mm | Smiths Healthcare Manufacturing S.A. De C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico | N/A | 46967 | IIa | 5 |
| 130. | 100/141/025 | Tracheal Tube M/Eye Uncuffed Siliconised Oral/Nasal 2.5mm | Smiths Healthcare Manufacturing S.A. De C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico | N/A | 46967 | IIa | 5 |
| 131. | 100/141/030 | Tracheal Tube M/Eye Uncuffed Siliconised Oral/Nasal 3.0mm | Smiths Healthcare Manufacturing S.A. De C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico | N/A | 46967 | IIa | 5 |

| Num | Catalog Number | Product Description | Manufacturing Site | UMDNS (if applicable) | GMDN Code | EU Risk Class | EU Rule |
|---|---|---|---|---|---|---|---|
| 132. | 100/141/035 | Tracheal Tube M/Eye Uncuffed Siliconised Oral/Nasal 3.5mm | Smiths Healthcare Manufacturing S.A. De C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico | N/A | 46967 | IIa | 5 |
| 133. | 100/141/040 | Tracheal Tube M/Eye Uncuffed Siliconised Oral/Nasal 4.0mm | Smiths Healthcare Manufacturing S.A. De C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico | N/A | 46967 | IIa | 5 |
| 134. | 100/141/045 | Tracheal Tube M/Eye Uncuffed Siliconised Oral/Nasal 4.5mm | Smiths Healthcare Manufacturing S.A. De C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico | N/A | 46967 | IIa | 5 |
| 135. | 100/141/050 | Tracheal Tube M/Eye Uncuffed Siliconised Oral/Nasal 5.0mm | Smiths Healthcare Manufacturing S.A. De C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico | N/A | 46967 | IIa | 5 |
| 136. | 100/141/055 | Tracheal Tube M/Eye Uncuffed Siliconised Oral/Nasal 5.5mm | Smiths Healthcare Manufacturing S.A. De C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico | N/A | 46967 | IIa | 5 |
| 137. | 100/141/060 | Tracheal Tube M/Eye Uncuffed Siliconised Oral/Nasal 6.0mm | Smiths Healthcare Manufacturing S.A. De C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico | N/A | 46967 | IIa | 5 |
| 138. | 100/141/065 | Tracheal Tube M/Eye Uncuffed Siliconised Oral/Nasal 6.5mm | Smiths Healthcare Manufacturing S.A. De C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico | N/A | 46967 | IIa | 5 |

| Num | Catalog Number | Product Description | Manufacturing Site | UMDNS (if applicable) | GMDN Code | EU Risk Class | EU Rule |
|---|---|---|---|---|---|---|---|
| 139. | 100/141/070 | Tracheal Tube M/Eye Uncuffed Siliconised Oral/Nasal 7.0mm | Smiths Healthcare Manufacturing S.A. De C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico | N/A | 46967 | IIa | 5 |
| 140. | 100/141/075 | Tracheal Tube M/Eye Uncuffed Siliconised Oral/Nasal 7.5mm | Smiths Healthcare Manufacturing S.A. De C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico | N/A | 46967 | IIa | 5 |
| 141. | 100/141/080 | Tracheal Tube M/Eye Uncuffed Siliconised Oral/Nasal 8.0mm | Smiths Healthcare Manufacturing S.A. De C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico | N/A | 46967 | IIa | 5 |
| 142. | 100/141/085 | Tracheal Tube M/Eye Uncuffed Siliconised Oral/Nasal 8.5mm | Smiths Healthcare Manufacturing S.A. De C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico | N/A | 46967 | IIa | 5 |
| 143. | 100/141/090 | Tracheal Tube M/Eye Uncuffed Siliconised Oral/Nasal 9.0mm | Smiths Healthcare Manufacturing S.A. De C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico | N/A | 46967 | IIa | 5 |
| 144. | 100/141/095 | Tracheal Tube M/Eye Uncuffed Siliconised Oral/Nasal 9.5mm | Smiths Healthcare Manufacturing S.A. De C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico | N/A | 46967 | IIa | 5 |
| 145. | 100/166/050 | Tracheal Tube Siliconised Pvc Soft-Seal Cuff Oral/Nasal5.0mm | Smiths Healthcare Manufacturing S.A. De C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico | N/A | 46967 | IIa | 5 |

| Num | Catalog Number | Product Description | Manufacturing Site | UMDNS (if applicable) | GMDN Code | EU Risk Class | EU Rule |
|---|---|---|---|---|---|---|---|
| 146. | 100/166/055 | Tracheal Tube Siliconised PVC Soft-Seal Cuff Oral/Nasal5.5mm | Smiths Healthcare Manufacturing S.A. De C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico | N/A | 46967 | IIa | 5 |
| 147. | 100/166/060 | Tracheal Tube Siliconised PVC Soft-Seal Cuff Oral/Nasal6.0mm | Smiths Healthcare Manufacturing S.A. De C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico | N/A | 46967 | IIa | 5 |
| 148. | 100/166/065 | Tracheal Tube Siliconised PVC Soft-Seal Cuff Oral/Nasal6.5mm | Smiths Healthcare Manufacturing S.A. De C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico | N/A | 46967 | IIa | 5 |
| 149. | 100/166/070 | Tracheal Tube Siliconised PVC Soft-Seal Cuff Oral/Nasal7.0mm | Smiths Healthcare Manufacturing S.A. De C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico | N/A | 46967 | IIa | 5 |
| 150. | 100/166/075 | Tracheal Tube Siliconised PVC Soft-Seal Cuff Oral/Nasal7.5mm | Smiths Healthcare Manufacturing S.A. De C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico | N/A | 46967 | IIa | 5 |
| 151. | 100/166/080 | Tracheal Tube Siliconised PVC Soft-Seal Cuff Oral/Nasal8.0mm | Smiths Healthcare Manufacturing S.A. De C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico | N/A | 46967 | IIa | 5 |
| 152. | 100/166/085 | Tracheal Tube Siliconised PVC Soft-Seal Cuff Oral/Nasal8.5mm | Smiths Healthcare Manufacturing S.A. De C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico | N/A | 46967 | IIa | 5 |

| Num | Catalog Number | Product Description | Manufacturing Site | UMDNS (if applicable) | GMDN Code | EU Risk Class | EU Rule |
|---|---|---|---|---|---|---|---|
| 153. | 100/166/090 | Tracheal Tube Siliconised PVC Soft-Seal Cuff Oral/Nasal9.0mm | Smiths Healthcare Manufacturing S.A. De C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico | N/A | 46967 | IIa | 5 |
| 154. | 100/166/095 | Tracheal Tube Siliconised PVC Soft-Seal Cuff Oral/Nasal9.5mm | Smiths Healthcare Manufacturing S.A. De C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico | N/A | 46967 | IIa | 5 |
| 155. | 100/166/100 | Tracheal Tube Siliconised PVC Soft-Seal Oral/Nasal 10mm | Smiths Healthcare Manufacturing S.A. De C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico | N/A | 46967 | IIa | 5 |
| 156. | 100/179/050 | Tracheal Tube Ivory Nasal Soft Seal Cuff 5.0mm | Smiths Healthcare Manufacturing S.A. De C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico | N/A | 46967 | IIa | 5 |
| 157. | 100/179/055 | Tracheal Tube Ivory Nasal Soft Seal Cuff 5.5mm | Smiths Healthcare Manufacturing S.A. De C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico | N/A | 46967 | IIa | 5 |
| 158. | 100/179/060 | Tracheal Tube Ivory Nasal Soft Seal Cuff 6.0mm | Smiths Healthcare Manufacturing S.A. De C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico | N/A | 46967 | IIa | 5 |
| 159. | 100/179/065 | Tracheal Tube Ivory Nasal Soft Seal Cuff 6.5mm | Smiths Healthcare Manufacturing S.A. De C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico | N/A | 46967 | IIa | 5 |

| Num | Catalog Number | Product Description | Manufacturing Site | UMDNS (if applicable) | GMDN Code | EU Risk Class | EU Rule |
|---|---|---|---|---|---|---|---|
| 160. | 100/179/070 | Tracheal Tube Ivory Nasal Soft Seal Cuff 7.0mm | Smiths Healthcare Manufacturing S.A. De C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico | N/A | 46967 | IIa | 5 |
| 161. | 100/179/075 | Tracheal Tube Ivory Nasal Soft Seal Cuff 7.5mm | Smiths Healthcare Manufacturing S.A. De C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico | N/A | 46967 | IIa | 5 |
| 162. | 100/179/080 | Tracheal Tube Ivory Nasal Soft Seal Cuff 8.0mm | Smiths Healthcare Manufacturing S.A. De C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico | N/A | 46967 | IIa | 5 |
| 163. | 100/179/085 | Tracheal Tube Ivory Nasal Soft Seal Cuff 8.5mm | Smiths Healthcare Manufacturing S.A. De C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico | N/A | 46967 | IIa | 5 |
| 164. | 100/179/090 | Tracheal Tube Ivory Nasal Soft Seal Cuff 9.0mm | Smiths Healthcare Manufacturing S.A. De C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico | N/A | 46967 | IIa | 5 |
| 165. | 100/189/060 | Sacett, Suction Above Cuff Tracheal Tube 6.0 | Smiths Healthcare Manufacturing S.A. De C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico | N/A | 47691 | IIa | 5 |
| 166. | 100/189/065 | Sacett, Suction Above Cuff Tracheal Tube 6.5 | Smiths Healthcare Manufacturing S.A. De C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico | N/A | 47691 | IIa | 5 |

| Num | Catalog Number | Product Description | Manufacturing Site | UMDNS (if applicable) | GMDN Code | EU Risk Class | EU Rule |
|---|---|---|---|---|---|---|---|
| 167. | 100/189/070 | Sacett, Suction Above Cuff Tracheal Tube 7.0 | Smiths Healthcare Manufacturing S.A. De C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico | N/A | 47691 | IIa | 5 |
| 168. | 100/189/075 | Sacett, Suction Above Cuff Tracheal Tube 7.5 | Smiths Healthcare Manufacturing S.A. De C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico | N/A | 47691 | IIa | 5 |
| 169. | 100/189/080 | Sacett, Suction Above Cuff Tracheal Tube 8.0 | Smiths Healthcare Manufacturing S.A. De C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico | N/A | 47691 | IIa | 5 |
| 170. | 100/189/085 | Sacett, Suction Above Cuff Tracheal Tube 8.5 | Smiths Healthcare Manufacturing S.A. De C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico | N/A | 47691 | IIa | 5 |
| 171. | 100/189/090 | Sacett, Suction Above Cuff Tracheal Tube 9.0 | Smiths Healthcare Manufacturing S.A. De C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico | N/A | 47691 | IIa | 5 |
| 172. | 100/190/050 | Microlaryngeal Tube Profile Cuff Ivory Oral/Nasal Id 5.0mm | Smiths Healthcare Manufacturing S.A. De C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico | N/A | 46967 | IIa | 5 |
| 173. | 100/199/050 | Tracheal Tube Clear Murphy Eyesoft Seal Cuff 5.0mm | Smiths Healthcare Manufacturing S.A. De C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico | N/A | 46967 | IIa | 5 |

| Num | Catalog Number | Product Description | Manufacturing Site | UMDNS (if applicable) | GMDN Code | EU Risk Class | EU Rule |
|---|---|---|---|---|---|---|---|
| 174. | 100/199/055 | Tracheal Tube Clear Murphy Eyesoft-Seal Cuff 5.5mm | Smiths Healthcare Manufacturing S.A. De C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico | N/A | 46967 | IIa | 5 |
| 175. | 100/199/060 | Tracheal Tube Clear Murphy Eyesoft-Seal Cuff 6.0mm | Smiths Healthcare Manufacturing S.A. De C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico | N/A | 46967 | IIa | 5 |
| 176. | 100/199/065 | Tracheal Tube Clear Murphy Eyesoft-Seal Cuff 6.5mm | Smiths Healthcare Manufacturing S.A. De C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico | N/A | 46967 | IIa | 5 |
| 177. | 100/199/070 | Tracheal Tube Clear Murphy Eyesoft-Seal Cuff 7.0mm | Smiths Healthcare Manufacturing S.A. De C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico | N/A | 46967 | IIa | 5 |
| 178. | 100/199/075 | Tracheal Tube Clear Murphy Eyesoft-Seal Cuff 7.5mm | Smiths Healthcare Manufacturing S.A. De C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico | N/A | 46967 | IIa | 5 |
| 179. | 100/199/080 | Tracheal Tube Clear Murphy Eyesoft-Seal Cuff 8.0mm | Smiths Healthcare Manufacturing S.A. De C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico | N/A | 46967 | IIa | 5 |
| 180. | 100/199/085 | Tracheal Tube Clear Murphy Eyesoft-Seal Cuff 8.5mm | Smiths Healthcare Manufacturing S.A. De C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico | N/A | 46967 | IIa | 5 |

| Num | Catalog Number | Product Description | Manufacturing Site | UMDNS (if applicable) | GMDN Code | EU Risk Class | EU Rule |
|---|---|---|---|---|---|---|---|
| 181. | 100/199/090 | Tracheal Tube Clear Murphy Eyesoft-Seal Cuff 9.0mm | Smiths Healthcare Manufacturing S.A. De C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico | N/A | 46967 | IIa | 5 |
| 182. | 100/199/095 | Tracheal Tube Clear Murphy Eyesoft-Seal Cuff 9.5mm | Smiths Healthcare Manufacturing S.A. De C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico | N/A | 46967 | IIa | 5 |
| 183. | 100/199/100 | Tracheal Tube Clear Murphy Eyesoft Seal Cuf 10.0mm | Smiths Healthcare Manufacturing S.A. De C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico | N/A | 46967 | IIa | 5 |
| 184. | 100/430/150 | Cole Neonatal Tube, 1.5mm | Smiths Healthcare Manufacturing SA de CV Carretera Miguel Aleman Km 21.7, Parque Industrial Monterrey, Apodaca NL CP 66603 Mexico | N/A | 46967 | IIa | 5 |
| 185. | 100/430/200 | Cole Neonatal Tube, 2mm | Smiths Healthcare Manufacturing SA de CV Carretera Miguel Aleman Km 21.7, Parque Industrial Monterrey, Apodaca NL CP 66603 Mexico | N/A | 46967 | IIa | 5 |
| 186. | 100/430/250 | Cole Neonatal Tube, 2.5mm | Smiths Healthcare Manufacturing SA de CV Carretera Miguel Aleman Km 21.7, Parque Industrial Monterrey, Apodaca NL CP 66603 Mexico | N/A | 46967 | IIa | 5 |

| Num | Catalog Number | Product Description | Manufacturing Site | UMDNS (if applicable) | GMDN Code | EU Risk Class | EU Rule |
|---|---|---|---|---|---|---|---|
| 187. | 100/430/300 | Cole Neonatal Tube, 3mm | Smiths Healthcare Manufacturing SA de CV Carretera Miguel Aleman Km 21.7, Parque Industrial Monterrey, Apodaca NL CP 66603 Mexico | N/A | 46967 | IIa | 5 |
| 188. | 100/430/350 | Cole Neonatal Tube, 3.5mm | Smiths Healthcare Manufacturing SA de CV Carretera Miguel Aleman Km 21.7, Parque Industrial Monterrey, Apodaca NL CP 66603 Mexico | N/A | 46967 | IIa | 5 |
| 189. | 100/430/400 | Cole Neonatal Tube, 4mm | Smiths Healthcare Manufacturing SA de CV Carretera Miguel Aleman Km 21.7, Parque Industrial Monterrey, Apodaca NL CP 66603 Mexico | N/A | 46967 | IIa | 5 |
| 190. | 100/611/020 | Tracheal Tube And Holder Kit Paediatric Siliconised 2.0mm | Smiths Healthcare Manufacturing S.A. De C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico | N/A | 46967 | IIa | 5 |
| 191. | 100/611/025 | Tracheal Tube And Holder Kit Paediatric Siliconised 2.5mm | Smiths Healthcare Manufacturing S.A. De C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico | N/A | 46967 | IIa | 5 |
| 192. | 100/611/030 | Tracheal Tube And Holder Kit Paediatric Siliconised 3.0mm | Smiths Healthcare Manufacturing S.A. De C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico | N/A | 46967 | IIa | 5 |
| 193. | 100/611/035 | Tracheal Tube And Holder Kit Paediatric Siliconised 3.5mm | Smiths Healthcare Manufacturing S.A. De C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico | N/A | 46967 | IIa | 5 |

| Num | Catalog Number | Product Description | Manufacturing Site | UMDNS (if applicable) | GMDN Code | EU Risk Class | EU Rule |
|---|---|---|---|---|---|---|---|
| 194. | 100/611/040 | Eal Tube And Holder Kit Paediatric Siliconised 4.0mm | Smiths Healthcare Manufacturing S.A. De C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico | N/A | 46967 | IIa | 5 |
| 195. | 100/611/045 | Tracheal Tube And Holder Kit Paediatric Siliconised 4.5mm | Smiths Healthcare Manufacturing S.A. De C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico | N/A | 46967 | IIa | 5 |
| 196. | H4003PS | Neonatal/Paed. Intubation Kit 3.5mm Murphy, Lds 15mm Conn | Smiths Healthcare Manufacturing S.A. De C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico | N/A | 46967 | IIa | 5 |
| 197. | H4003S | Neonatal/Paed. Intubation Kit 3.5mm Murphy,15mm Conn, Holder | Smiths Healthcare Manufacturing S.A. De C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico | N/A | 46967 | IIa | 5 |
| 198. | H4004S | Neonatal/Paed. Intubation Kit 4.0mm Murphy,15mm Conn, Holder | Smiths Healthcare Manufacturing S.A. De C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico | N/A | 46967 | IIa | 5 |
| 199. | H4005S | Neonatal/Paed. Intubation Kit 4.5mm Murphy,15mm Conn, Holder | Smiths Healthcare Manufacturing S.A. De C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico | N/A | 46967 | IIa | 5 |
| 200. | H4006S | Neonatal/Paed. Intubation Kit 5.0mm Murphy 15mm Conn, Holder | Smiths Healthcare Manufacturing S.A. De C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico | N/A | 46967 | IIa | 5 |

| Num | Catalog Number | Product Description | Manufacturing Site | UMDNS (if applicable) | GMDN Code | EU Risk Class | EU Rule |
|---|---|---|---|---|---|---|---|
| 201. | H4021PS | Neonatal/Paed. Endotrach Tube 2.5mm Murphy, Lds 15mm Connector | Smiths Healthcare Manufacturing S.A. De C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico | N/A | 46967 | IIa | 5 |
| 202. | H4021S | Neonatal/Paed. Endotrach Tube 2.5mm Murphy 15mm Connector | Smiths Healthcare Manufacturing S.A. De C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico | N/A | 46967 | IIa | 5 |
| 203. | H4022PS | Neonatal/Paed. Endotrach Tube 3.0mm Murphy, Lds 15mm Connector | Smiths Healthcare Manufacturing S.A. De C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico | N/A | 46967 | IIa | 5 |
| 204. | H4022S | Neonatal/Paed. Endotrach Tube 3.0mm Murphy 15mm Connector | Smiths Healthcare Manufacturing S.A. De C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico | N/A | 46967 | IIa | 5 |
| 205. | H4023PS | Neonatal/Paed. Endotrach Tube 3.5mm Murphy, Lds 15mm Connector | Smiths Healthcare Manufacturing S.A. De C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico | N/A | 46967 | IIa | 5 |
| 206. | H4023S | Neonatal/Paed. Endotrach Tube 3.5mm Murphy 15mm Connector | Smiths Healthcare Manufacturing S.A. De C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico | N/A | 46967 | IIa | 5 |
| 207. | H4024S | Neonatal/Paed. Endotrach Tube 4.0mm Murphy 15mm Connector | Smiths Healthcare Manufacturing S.A. De C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico | N/A | 46967 | IIa | 5 |

| Num | Catalog Number | Product Description | Manufacturing Site | UMDNS (if applicable) | GMDN Code | EU Risk Class | EU Rule |
|---|---|---|---|---|---|---|---|
| 208. | H4025S | Neonatal/Paed. Endotrach Tube 4.5mm Murphy 15mm Connector | Smiths Healthcare Manufacturing S.A. De C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico | N/A | 46967 | IIa | 5 |
| 209. | H4026S | Neonatal/Paed. Endotrach Tube 5.0mm Murphy 15mm Connector | Smiths Healthcare Manufacturing S.A. De C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico | N/A | 46967 | IIa | 5 |

**Appendix 2: Revision History**

| Revision Number | Summary of Changes / Additions | Created / Revised by | Date (DD-MMM-YYYY Format) |
|---|---|---|---|
| 005 | GMDN correction - 47132 replaced with 47121.<br>Product description and classification correction for L957 and L958. Removal of obsolete codes: 100/420/150<br>Addition of new codes: 100/113/035, 100/113/040 & 100/113/050 | N/A | 18-NOV-2013 |
| 006 | Updating DoC to the latest Template, Updated EC Cert info; confirmed the GMDN codes; removed 100/420/xxx (Infant Resuscitation tube sets used in Service); remove 100/150/xxx which are IAWA OBL products covered under S1029 | Mitchell Madsen | 23-JAN-2016 |
| 007 | Change document number format from SXXX to DoCXXX to load documents into Agile. No updates made to content of this document with the exception of the document number from S1028 to DoC-034 and revision from 006 to 007 and added STED # to header for traceability to STED. Removed Notified Body address for consistency across all DoCs. | Callie Frick | 05-JUN-2017 |
| 008 | Updated DoC to the latest Template in Agile. Updated the Notified Body from Intertek to BSI, updated the CE Certificate from 053-01 A CE to CE 661325, updated the Notified Body Number from 0473 to 0086. Removed the Issued By date for the Certificate Number. Changed Signatory from James Taufen to Stacy Novak. | Mitchell Madsen | 24-OCT-2017 |
| 009-108 | Per DVSOP2005: When converting documents and parts in production lifecycle from the Rev 000 format to Rev 100 format, use the next revision and replace the leading 0 with a 1 | Kristen Evenson | 25-MAY-2018 |
| 109 | Corrected a typo in the Legal Manufacturer name from Boudary Road, Hythe to Boundary Road, Hythe.<br>SKUs H4001PS, H4001S, H4002PS and H4002S were removed as they are now obsolete and no product is available for distribution. Changed the Manufacturing Site from Tijuana to Monterrey for the following codes: 100/107/030, 100/107/035, 100/107/040, 100/107/045, 100/107/050, | Kristen Evenson | 25-MAY-2018 |

| Revision Number | Summary of Changes / Additions | Created / Revised by | Date (DD-MMM-YYYY Format) |
|---|---|---|---|
| | 100/109/055, 100/109/060, 100/109/065, 100/109/070, 100/109/075, 100/109/080, 100/109/085 and 100/109/090. Updated product descriptions to correspond to descriptions on product labels. Corrected Product Tradenames. Changed Signatory from Stacy Novak to Donna Semlak. | | |
| 110 | Updated to newest template revision (003 to 104).<br>Updated STED title from “Intubation Systems Endotracheal Tubes” to “Intubation and Endotracheal Tubes” to reflect the STED’s description in Agile.<br>Changed the legal manufacturer from MHYT to MMSP as per FM-DVSOP8005-05<br>Added Hranice, Czech Republic as EU Representative. An EU Representative is needed if a product is commercially distributed in the EU and not manufactured in the EU. Since the Legal Manufacturer is changing to MMSP, an EU Representative is needed.<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.<br>Changed the EC Certificate from CE 661325 to CE 669121 due to the Legal Manufacturer change.<br>Changed Product Scope from “Intubation Systems” to “Sterile and non-sterile Applications for patient Intubation” to align with EC Certificate 669121.<br>Revised SKU descriptions to match description field in Agile.<br>Deleted L957 and L958 from Appendix 1. Both L957 and L958 are Post-Phase Out.<br>Changed the manufacturing site in Appendix 1 from Tijuana to Monterrey for SKU 100/430/150, 100/430/200, 100/430/250, 100/430/300, 100/430/350, and 100/430/400. Confirmed with Laura Ruvalcaba, Quality System Manager at Tijuana site, that these SKUs are manufactured at Monterrey site.<br>Revised the Manufacturing Site addresses for Monterrey and Tijuana to match the address listed on EC Certificate 669121. | Thomas Saladin/Alicia Wilson | 02-AUG-2019 |