

	Declaration of Conformity	DoC-137 Revision Number: 140
	S1188: Tracheostomy and Laryngectomy Tubes	

Manufacturer: Smiths Medical ASD, Inc.
6000 Nathan Lane North
Minneapolis, Minnesota 55442 USA

EU Representative: Smiths Medical Czech Republic a. s.
Olomoucká 306,
Hranice 1 - Město,
753 01 Hranice, Czech Republic

Product Tradename(s): Bivona®, Hyperflex®, FlexTend™, Aire-Cuf®, TTS™, Fome-Cuf®

Product Scope: Sterile Tracheostomy Tubes and Kits

Conformity Assessment Route: Annex II (excluding Section 4)

Notified Body: BSI Healthcare
Medical Devices Certification
Notified Body #2797

EC Certificate Number: CE 669121

Start of CE-Marking: JUL, 2002

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: _____



Date: _____



Name: Stacy Novak

Title: Sr. Manager, Regulatory Operations

Location of Signatory: Minneapolis, MN, USA

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Appendix 1: Product List

Num	Catalog Number	Product Description	Manufacturing Site	UMDNS (if applicable)	GMDN Code	EU Risk Class	EU Rule
1.	60A150	ADULT TRACHEOSTOMY 5.0MM UNCUFFED	Smiths Medical ASD, Inc. 5700 West 23 rd Avenue, Gary, IN 46406 USA	N/A	38792	IIb	5
2.	60A160	ADULT TRACHEOSTOMY 6.0MM UNCUFFED 1/EA	Smiths Medical ASD, Inc. 5700 West 23 rd Avenue, Gary, IN 46406 USA	N/A	38792	IIb	5
3.	60A170	ADULT TRACHEOSTOMY 7.0MM UNCUFFED 1/EA	Smiths Medical ASD, Inc. 5700 West 23 rd Avenue, Gary, IN 46406 USA	N/A	38792	IIb	5
4.	60A180	ADULT TRACHEOSTOMY 8.0MM UNCUFFED 1/EA	Smiths Medical ASD, Inc. 5700 West 23 rd Avenue, Gary, IN 46406 USA	N/A	38792	IIb	5
5.	60A190	ADULT TRACHEOSTOMY 9.0MM UNCUFFED 1/EA	Smiths Medical ASD, Inc. 5700 West 23 rd Avenue, Gary, IN 46406 USA	N/A	38792	IIb	5
6.	60AFHXL60	6.0 MM XL FIXED HYPERFLEX U/C +1/EA	Smiths Medical ASD, Inc. 5700 West 23 rd Avenue, Gary, IN 46406 USA	N/A	63798	IIb	5
7.	60AFHXL70	7.0 MM XL FIXED HYPERFLEX U/C + 1/EA	Smiths Medical ASD, Inc. 5700 West 23 rd Avenue, Gary, IN 46406 USA	N/A	63798	IIb	5
8.	60AFHXL80	8.0 MM XL FIXED HYPERFLEX U/C + 1/EA	Smiths Medical ASD, Inc. 5700 West 23 rd Avenue, Gary, IN 46406 USA	N/A	63798	IIb	5
9.	60AFHXL90	9.0 MM XL FIXED HYPERFLEX U/C + 1/EA	Smiths Medical ASD, Inc. 5700 West 23 rd Avenue, Gary, IN 46406 USA	N/A	63798	IIb	5
10.	60HA25	2.5MM HYPERFLEX TRACHEOSTOMY UNCUFFED, ADJUST. NECK FLANGE 1/EA	Smiths Medical ASD, Inc. 5700 West 23 rd Avenue, Gary, IN 46406 USA	N/A	47657	IIa	5
11.	60HA30	3.0MM HYPERFLEX TRACHEOSTOMY UNCUFFED, ADJUST. NECK FLANGE 1/EA	Smiths Medical ASD, Inc. 5700 West 23 rd Avenue, Gary, IN 46406 USA	N/A	47657	IIa	5
12.	60HA35	3.5MM HYPERFLEX TRACHEOSTOMY UNCUFFED, ADJUST. NECK FLANGE 1/EA	Smiths Medical ASD, Inc. 5700 West 23 rd Avenue, Gary, IN 46406 USA	N/A	47657	IIa	5

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Num	Catalog Number	Product Description	Manufacturing Site	UMDNS (if applicable)	GMDN Code	EU Risk Class	EU Rule
13.	60HA40	4.0MM HYPERFLEX TRACHEOSTOMY UNCUFFED, ADJUST. NECK FLANGE 1/EA	Smiths Medical ASD, Inc. 5700 West 23 rd Avenue, Gary, IN 46406 USA	N/A	47657	Ila	5
14.	60HA45	4.5MM HYPERFLEX TRACHEOSTOMY UNCUFFED, ADJUST. NECK FLANGE 1/EA	Smiths Medical ASD, Inc. 5700 West 23 rd Avenue, Gary, IN 46406 USA	N/A	47657	Ila	5
15.	60HA50	5.0MM HYPERFLEX TRACHEOSTOMY UNCUFFED, ADJUST. NECK FLANGE 1/EA	Smiths Medical ASD, Inc. 5700 West 23 rd Avenue, Gary, IN 46406 USA	N/A	47657	Ila	5
16.	60HA55	5.5MM HYPERFLEX TRACHEOSTOMY UNCUFFED, ADJUST. NECK FLANGE 1/EA	Smiths Medical ASD, Inc. 5700 West 23 rd Avenue, Gary, IN 46406 USA	N/A	47657	Ila	5
17.	60N025	NEONATAL TRACHEOSTOMY TUBE + 1/EA	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	N/A	63798	IIb	5
18.	60N030	NEONATAL TRACH TUBE + 1/EA	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	N/A	63798	IIb	5
19.	60N035	NEONATAL TRACH TUBE + 1/EA	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	N/A	63798	IIb	5
20.	60N040	NEONATAL TRACH TUBE + 1/EA	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	N/A	63798	IIb	5
21.	60NFP25	NEONATAL TRACHEOSTOMY TUBE 2.5FLEXTEND PLUS 1/EA	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	N/A	63798	IIb	5

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Num	Catalog Number	Product Description	Manufacturing Site	UMDNS (if applicable)	GMDN Code	EU Risk Class	EU Rule
22.	60NFP30	NEONATAL TRACHEOSTOMY TUBE 3.0FLEXTEND PLUS 1/EA	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	N/A	63798	IIb	5
23.	60NFP35	NEONATAL TRACHEOSTOMY TUBE 3.5FLEXTEND PLUS 1/EA	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	N/A	63798	IIb	5
24.	60NFP40	NEONATAL TRACHEOSTOMY TUBE 4.0FLEXTEND PLUS 1/EA	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	N/A	63798	IIb	5
25.	60NFPS25	2.5MM UNCUFFED NEONATAL FLEXTEND PLUS TRACHEOSTOMY TUBE W/NEO STRAIGHT STRAP	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	N/A	63798	IIb	5
26.	60NFPS30	3.0MM FLEXTEND NEO STRAIGHT TRACH TUBE	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	N/A	63798	IIb	5
27.	60NFPS35	3.5MM FLEXTEND NEO STRAIGHT TRACH TUBE	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	N/A	63798	IIb	5
28.	60NFPS40	4.0MM FLEXTEND NEO STRAIGHT TRACH TUBE	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	N/A	63798	IIb	5

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29.	60P025	PAED. TRACHEOSTOMY TUBE 2.5MM UNCUFFED 1/EA	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	N/A	38792	IIb	5
30.	60P030	PAED. TRACHEOSTOMY TUBE 3.0MM UNCUFFED 1/EA	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	N/A	38792	IIb	5
31.	60P035	PAED. TRACHEOSTOMY TUBE 3.5MM UNCUFFED 1/EA	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	N/A	38792	IIb	5
32.	60P040	PAED. TRACHEOSTOMY TUBE 4.0MM UNCUFFED 1/EA	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	N/A	38792	IIb	5
33.	60P045	PAED. TRACHEOSTOMY TUBE 4.5MM UNCUFFED 1/EA	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	N/A	38792	IIb	5
34.	60P050	PAED. TRACHEOSTOMY TUBE 5.0MM UNCUFFED 1/EA	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	N/A	38792	IIb	5
35.	60P055	PAED. TRACHEOSTOMY TUBE 5.5MM UNCUFFED 1/EA	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	N/A	38792	IIb	5

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36.	60PFP40	PAED. TRACHEOSTOMY TUBE 4.0MM FLEXTEND PLUS 1/EA	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	N/A	63798	IIb	5
37.	60PFP45	PAED. TRACHEOSTOMY TUBE 4.5MM FLEXTEND PLUS 1/EA	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	N/A	63798	IIb	5
38.	60PFP50	PAED. TRACHEOSTOMY TUBE 5.0MM FLEXTEND PLUS 1/EA	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	N/A	63798	IIb	5
39.	60PFP55	PAED. TRACHEOSTOMY TUBE 5.5MM FLEXTEND PLUS 1/EA	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	N/A	63798	IIb	5
40.	60PFP60	6.0MM FLEXTEND PEDIATRIC PLUS VEE TRACH TUBE	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	N/A	63798	IIb	5
41.	60PFPS40	4.0MM FLEXTEND PEDIATRIC PLUS STRAIGHT TRACH TUBE	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	N/A	63798	IIb	5
42.	60PFPS45	4.5MM FLEXTEND PEDIATRIC PLUS STRAIGHT TRACH TUBE	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	N/A	63798	IIb	5

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43.	60PFPS50	5.0MM FLEXTEND PEDIATRIC PLUS STRAIGHT TRACH TUBE	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	N/A	63798	IIb	5
44.	60PFPS55	5.5MM FLEXTEND PEDIATRIC PLUS STRIAGHT TRACH TUBE	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	N/A	63798	IIb	5
45.	60PFPS60	6.0MM FLEXTEND PEDIATRIC PLUS STRAIGHT TRACH TUBE	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	N/A	63798	IIb	5
46.	60PFS25	PAED. TRACHEOSTOMY TUBE 2.5MM STANDARD FLEXTEND PLUS 1/EA	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	N/A	63798	IIb	5
47.	60PFS30	PAED. TRACHEOSTOMY TUBE 3.0MM STANDARD FLEXTEND PLUS 1/EA	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	N/A	63798	IIb	5
48.	60PFS35	PAED. TRACHEOSTOMY TUBE 3.5MM STANDARD FLEXTEND PLUS 1/EA	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	N/A	63798	IIb	5
49.	60PFS40	PAED. TRACHEOSTOMY TUBE 4.0MM STANDARD FLEXTEND PLUS 1/EA	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	N/A	63798	IIb	5

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50.	60PFS45	PAED. TRACHEOSTOMY TUBE 4.5MM STANDARD FLEXTEND PLUS 1/EA	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	N/A	63798	IIb	5
51.	60PFS50	PAED. TRACHEOSTOMY TUBE 5.0MM STANDARD FLEXTEND PLUS 1/EA	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	N/A	63798	IIb	5
52.	60PFS55	PAED. TRACHEOSTOMY TUBE 5.5MM STANDARD FLEXTEND PLUS 1/EA	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	N/A	63798	IIb	5
53.	60PFSS25	2.5MM PEDIATRIC UNCUFFED FLEXTEND PLUS TRACHEOSTOMY TUBE WITH NEONATE STRAIGHT NECKSTRAP	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	N/A	63798	IIb	5
54.	60PFSS30	3.0MM FLEXTEND PEDIATRIC STANDARD STRAIGHT TRACH TUBE	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	N/A	63798	IIb	5
55.	60PFSS35	3.5MM FLEXTEND PEDIATRIC STANDARD STRAIGHT TRACH TUBE	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	N/A	63798	IIb	5
56.	60PFSS40	4.0MM FLEXTEND PEDIATRIC STANDARD STRAIGHT TRACH TUBE TRACH TUBE	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	N/A	63798	IIb	5

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57.	60PFSS45	4.5MM FLEXTEND PEDIATRIC STANDARD STRAIGHT TRACH TUBE	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	N/A	63798	IIb	5
58.	60PFSS50	5.0MM FLEXTEND PEDIATRIC STANDARD STRAIGHT TRACH TUBE	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	N/A	63798	IIb	5
59.	60PFSS55	5.5MM FLEXTEND PEDIATRIC STANDARD STRAIGHT TRACH TUBE	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	N/A	63798	IIb	5
60.	60SN025	2.5 UNCUFFED NEONATAL TRACHEOSTOMY TUBE 1/EA	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	N/A	63798	IIb	5
61.	60SN030	3.0 UNCUFFED NEONATAL TRACHEOSTOMY TUBE 1/EA	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	N/A	63798	IIb	5
62.	60SN035	3.5 UNCUFFED NEONATAL TRACHEOSTOMY TUBE 1/EA	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	N/A	63798	IIb	5
63.	60SN040	4.0 UNCUFFED NEONATAL TRACHEOSTOMY TUBE 1/EA	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	N/A	63798	IIb	5

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64.	60SP025	2.5 UNCUFFED PEDIATRIC TRACHEOSTOMY TUBE 1/EA	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	N/A	38792	IIb	5
65.	60SP030	3.0 UNCUFFED PEDIATRIC TRACHEOSTOMY TUBE 1/EA	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	N/A	38792	IIb	5
66.	60SP035	3.5 UNCUFFED PEDIATRIC TRACHEOSTOMY TUBE 1/EA	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	N/A	38792	IIb	5
67.	60SP040	4.0 UNCUFFED PEDIATRIC TRACHEOSTOMY TUBE 1/EA	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	N/A	38792	IIb	5
68.	60SP045	4.5 UNCUFFED PEDIATRIC TRACHEOSTOMY TUBE 1/EA	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	N/A	38792	IIb	5
69.	60SP050	5.0 UNCUFFED PEDIATRIC TRACHEOSTOMY TUBE 1/EA	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	N/A	38792	IIb	5
70.	60SP055	5.5 UNCUFFED PEDIATRIC TRACHEOSTOMY TUBE 1/EA	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	N/A	38792	IIb	5

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71.	65N025	NEONATAL TRACHEOSTOMY TUBE + 1/EA	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	N/A	63798	IIb	5
72.	65N030	NEONATAL TRACHEOSTOMY TUBE + 1/EA	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	N/A	63798	IIb	5
73.	65N035	NEONATAL TRACHEOSTOMY TUBE + 1/EA	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	N/A	63798	IIb	5
74.	65N040	NEONATAL TRACHEOSTOMY TUBE + 1/EA	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	N/A	63798	IIb	5
75.	65P025	PAED. TRACHEOSTOMY TUBE 2.5MM AIRE-CUF 1/EA	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	N/A	63798	IIb	5
76.	65P030	PAED. TRACHEOSTOMY TUBE 3.0MM AIRE-CUF 1/EA	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	N/A	63798	IIb	5
77.	65P035	PAED, TRACHEOSTOMY TUBE 3.5mm AIRE-CUF 1/EA	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	N/A	63798	IIb	5

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78.	65P040	PAED. TRACHEOSTOMY TUBE 4.0MM AIRE-CUF 1/EA	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	N/A	63798	IIb	5
79.	65P045	PAED. TRACHEOSTOMY TUBE 4.5MM AIRE-CUF 1/EA	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	N/A	63798	IIb	5
80.	65P050	PAED. TRACHEOSTOMY TUBE 5.0MM AIRE-CUF 1/EA	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	N/A	63798	IIb	5
81.	65P055	PAED. TRACHEOSTOMY TUBE 5.5MM AIRE-CUF 1/EA	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	N/A	63798	IIb	5
82.	65SN025	2.5MM AIRE-CUF NEONATAL TRACHEOSTOMY TUBE 1/EA	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	N/A	63798	IIb	5
83.	65SN030	3.0MM AIRE-CUF NEONATAL TRACHEOSTOMY TUBE 1/EA	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	N/A	63798	IIb	5
84.	65SN035	3.5MM AIRE-CUF NEONATAL TRACHE 1/EA	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	N/A	63798	IIb	5

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Num	Catalog Number	Product Description	Manufacturing Site	UMDNS (if applicable)	GMDN Code	EU Risk Class	EU Rule
85.	65SN040	4.0MM AIRE-CUF NEONATAL TRACHEOSTOMY TUBE 1/EA	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	N/A	63798	IIb	5
86.	65SP025	2.5 AIRE-CUF PEDIATRIC TRACHEOSTOMY TUBE 1/EA	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	N/A	63798	IIb	5
87.	65SP030	3.0 AIRE-CUF PEDIATRIC TRACHEOSTOMY TUBE 1/EA	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	N/A	63798	IIb	5
88.	65SP035	3.5 AIRE-CUF PEDIATRIC TRACHEOSTOMY TUBE 1/EA	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	N/A	63798	IIb	5
89.	65SP040	4.0 AIRE-CUF PEDIATRIC TRACHEOSTOMY TUBE 1/EA	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	N/A	63798	IIb	5
90.	65SP045	4.5 AIRE-CUF PEDIATRIC TRACHEOSTOMY TUBE 1/EA	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	N/A	63798	IIb	5
91.	65SP050	5.0 AIRE-CUF PEDIATRIC TRACHEOSTOMY TUBE 1/EA	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	N/A	63798	IIb	5

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Num	Catalog Number	Product Description	Manufacturing Site	UMDNS (if applicable)	GMDN Code	EU Risk Class	EU Rule
92.	65SP055	5.5 AIRE-CUF PEDIATRIC TRACHEOSTOMY TUBE 1/EA	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	N/A	63798	IIb	5
93.	670150	TTS TRACHEOSTOMY TUBE 5.0MM TIGHT TO SHAFT CUFF 1/EA	Smiths Medical ASD, Inc. 5700 West 23 rd Avenue, Gary, IN 46406 USA	N/A	38792	IIb	5
94.	670160	TTS TRACHEOSTOMY TUBE 6.0MM TIGHT TO SHAFT CUFF 1/EA	Smiths Medical ASD, Inc. 5700 West 23 rd Avenue, Gary, IN 46406 USA	N/A	38792	IIb	5
95.	670170	TTS TRACHEOSTOMY TUBE 7.0MM TIGHT TO SHAFT CUFF 1/EA	Smiths Medical ASD, Inc. 5700 West 23 rd Avenue, Gary, IN 46406 USA	N/A	38792	IIb	5
96.	670175	TTS TRACHEOSTOMY TUBE 7.5MM TIGHT TO SHAFT CUFF 1/EA	Smiths Medical ASD, Inc. 5700 West 23 rd Avenue, Gary, IN 46406 USA	N/A	38792	IIb	5
97.	670180	TTS TRACHEOSTOMY TUBE 8.0MM TIGHT TO SHAFT CUFF 1/EA	Smiths Medical ASD, Inc. 5700 West 23 rd Avenue, Gary, IN 46406 USA	N/A	38792	IIb	5
98.	670185	TTS TRACHEOSTOMY TUBE 8.5MM TIGHT TO SHAFT CUFF 1/EA	Smiths Medical ASD, Inc. 5700 West 23 rd Avenue, Gary, IN 46406 USA	N/A	38792	IIb	5
99.	670190	TTS TRACHEOSTOMY TUBE 9.0MM TIGHT TO SHAFT CUFF 1/EA	Smiths Medical ASD, Inc. 5700 West 23 rd Avenue, Gary, IN 46406 USA	N/A	38792	IIb	5
100.	67FHXL60	6.0MM TTS FIXED SINGLE-PIECE HYPERFLEX	Smiths Medical ASD, Inc. 5700 West 23 rd Avenue, Gary, IN 46406 USA	N/A	63798	IIb	5
101.	67FHXL70	7.0MM TTS-FIXED SINGLE-PIECE HYPERFLEX	Smiths Medical ASD, Inc. 5700 West 23 rd Avenue, Gary, IN 46406 USA	N/A	63798	IIb	5
102.	67FHXL80	8.0MM TTS FIXED SINGLE-PIECE HYPERFLEX	Smiths Medical ASD, Inc. 5700 West 23 rd Avenue, Gary, IN 46406 USA	N/A	63798	IIb	5
103.	67FHXL90	9.0MM TTS FIXED SINGLE-PIECE HYPERFLEX	Smiths Medical ASD, Inc. 5700 West 23 rd Avenue, Gary, IN 46406 USA	N/A	63798	IIb	5

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Num	Catalog Number	Product Description	Manufacturing Site	UMDNS (if applicable)	GMDN Code	EU Risk Class	EU Rule
104.	67HA60	TTS TRACHEOSTOMY TUBE 6.0MM TIGHT TO SHFT ADJUST HYPERFLEX 1/EA	Smiths Medical ASD, Inc. 5700 West 23 rd Avenue, Gary, IN 46406 USA	N/A	47657	Ila	5
105.	67HA70	TTS TRACHEOSTOMY TUBE 7.0MM TIGHT TO SHFT ADJUST HYPERFLEX 1/EA	Smiths Medical ASD, Inc. 5700 West 23 rd Avenue, Gary, IN 46406 USA	N/A	47657	Ila	5
106.	67HA80	TTS TRACHEOSTOMY TUBE 8.0MM TIGHT TO SHFT ADJUST HYPERFLEX 1/EA	Smiths Medical ASD, Inc. 5700 West 23 rd Avenue, Gary, IN 46406 USA	N/A	47657	Ila	5
107.	67HA90	TTS TRACHEOSTOMY TUBE 9.0MM TIGHT TO SHFT ADJUST HYPERFLEX 1/EA	Smiths Medical ASD, Inc. 5700 West 23 rd Avenue, Gary, IN 46406 USA	N/A	47657	Ila	5
108.	67N025	TTS NEONATAL TRACH TUBE + 1/EA	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	N/A	63798	IIb	5
109.	67N030	TTS NEONATAL TRACH TUBE + 1/EA	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	N/A	63798	IIb	5
110.	67N035	TTS NEONATAL TRACH TUBE + 1/EA	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	N/A	63798	IIb	5
111.	67N040	TTS NEONATAL TRACHY TUBE 4.0MM TIGHT TO SHAFT CUFF 1/EA	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	N/A	63798	IIb	5
112.	67P025	TTS PEDIATRIC TRACH TUBE + 1/EA	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	N/A	38792	IIb	5

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Num	Catalog Number	Product Description	Manufacturing Site	UMDNS (if applicable)	GMDN Code	EU Risk Class	EU Rule
113.	67P030	TTS PEDIATRIC TRACH TUBE + 1/EA	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	N/A	38792	IIb	5
114.	67P035	TTS PEDIATRIC TRACH TUBE + 1/EA	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	N/A	38792	IIb	5
115.	67P040	TTS PEDIATRIC TRACH TUBE + 1/EA	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	N/A	38792	IIb	5
116.	67P045	TTS PEDIATRIC TRACH TUBE + 1/EA	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	N/A	38792	IIb	5
117.	67P050	TTS PEDIATRIC TRACH TUBE + 1/EA	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	N/A	38792	IIb	5
118.	67P055	TTS PEDIATRIC TRACH TUBE + 1/EA	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	N/A	38792	IIb	5
119.	67SN025	2.5 TTS CUFFED NEONATAL TRACHEOSTOMY TUBE 1/EA	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	N/A	63798	IIb	5

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Num	Catalog Number	Product Description	Manufacturing Site	UMDNS (if applicable)	GMDN Code	EU Risk Class	EU Rule
120.	67SN030	3.0 TTS CUFFED NEONATAL TRACHEOSTOMY TUBE 1/EA	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	N/A	63798	IIb	5
121.	67SN035	3.5 TTS CUFFED NEONATAL TRACHEOSTOMY TUBE 1/EA	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	N/A	63798	IIb	5
122.	67SN040	4.0 TTS CUFFED NEONATAL TRACHEOSTOMY TUBE 1/EA	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	N/A	63798	IIb	5
123.	67SP025	2.5 TTS CUFFED PEDIATRIC TRACHEOSTOMY TUBE 1/EA	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	N/A	38792	IIb	5
124.	67SP030	3.0 TTS CUFFED PEDIATRIC TRACHEOSTOMY TUBE 1/EA	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	N/A	38792	IIb	5
125.	67SP035	3.5 TTS CUFFED PEDIATRIC TRACHEOSTOMY TUBE 1/EA	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	N/A	38792	IIb	5
126.	67SP040	4.0 TTS CUFFED PEDIATRIC TRACHEOSTOMY TUBE 1/EA	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	N/A	38792	IIb	5

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Num	Catalog Number	Product Description	Manufacturing Site	UMDNS (if applicable)	GMDN Code	EU Risk Class	EU Rule
127.	67SP045	4.5 TTS CUFFED PEDIATRIC TRACHEOSTOMY TUBE 1/EA	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	N/A	38792	Iib	5
128.	67SP050	5.0 TTS CUFFED PEDIATRIC TRACHEOSTOMY TUBE 1/EA	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	N/A	38792	Iib	5
129.	67SP055	5.5 TTS CUFFED PEDIATRIC TRACHEOSTOMY TUBE 1/EA	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	N/A	38792	Iib	5
130.	750150	AIRE-CUF TRACHY TUBE 5.0MM MID-RANGE 1/EA	Smiths Medical ASD, Inc. 5700 West 23 rd Avenue, Gary, IN 46406 USA	N/A	38792	Iib	5
131.	750160	AIRE-CUF TRACHY TUBE 6.0MM MID-RANGE 1/EA	Smiths Medical ASD, Inc. 5700 West 23 rd Avenue, Gary, IN 46406 USA	N/A	38792	Iib	5
132.	750170	AIRE-CUF TRACHY TUBE 7.0MM MID-RANGE 1/EA	Smiths Medical ASD, Inc. 5700 West 23 rd Avenue, Gary, IN 46406 USA	N/A	38792	Iib	5
133.	750180	AIRE-CUF TRACHY TUBE 8.0MM MID-RANGE 1/EA	Smiths Medical ASD, Inc. 5700 West 23 rd Avenue, Gary, IN 46406 USA	N/A	38792	Iib	5
134.	750190	AIRE-CUF TRACHY TUBE 9.0MM MID-RANGE 1/EA	Smiths Medical ASD, Inc. 5700 West 23 rd Avenue, Gary, IN 46406 USA	N/A	38792	Iib	5
135.	750195	AIRE-CUF TRACHY TUBE 9.5MM MID-RANGE 1/EA	Smiths Medical ASD, Inc. 5700 West 23 rd Avenue, Gary, IN 46406 USA	N/A	38792	Iib	5
136.	755150	AIRE-CUF TRACHY TUBE 5.0MM MID-RANGE, TALK ATTACHMENT 1/EA	Smiths Medical ASD, Inc. 5700 West 23 rd Avenue, Gary, IN 46406 USA	N/A	38792	Iib	5

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Num	Catalog Number	Product Description	Manufacturing Site	UMDNS (if applicable)	GMDN Code	EU Risk Class	EU Rule
137.	755160	AIRE-CUF TRACHY TUBE 6.0MM MID-RANGE, TALK ATTACHMENT 1/EA	Smiths Medical ASD, Inc. 5700 West 23 rd Avenue, Gary, IN 46406 USA	N/A	38792	I Ib	5
138.	755170	AIRE-CUF TRACHY TUBE 7.0MM MID-RANGE, TALK ATTACHMENT 1/EA	Smiths Medical ASD, Inc. 5700 West 23 rd Avenue, Gary, IN 46406 USA	N/A	38792	I Ib	5
139.	755180	AIRE-CUF TRACHY TUBE 8.0MM MID-RANGE, TALK ATTACHMENT 1/EA	Smiths Medical ASD, Inc. 5700 West 23 rd Avenue, Gary, IN 46406 USA	N/A	38792	I Ib	5
140.	755190	AIRE-CUF TRACHY TUBE 9.0MM MID-RANGE, TALK ATTACHMENT 1/EA	Smiths Medical ASD, Inc. 5700 West 23 rd Avenue, Gary, IN 46406 USA	N/A	38792	I Ib	5
141.	755195	AIRE-CUF TRACHY TUBE 9.5MM MID-RANGE, TALK ATTACHMENT 1/EA	Smiths Medical ASD, Inc. 5700 West 23 rd Avenue, Gary, IN 46406 USA	N/A	38792	I Ib	5
142.	75FHXL60	6.0 MM XL FIXED HYPERFLEX MR AC + 1/EA	Smiths Medical ASD, Inc. 5700 West 23 rd Avenue, Gary, IN 46406 USA	N/A	63798	I Ib	5
143.	75FHXL70	7.0 MM XL FIXED HYPERFLEX MR AC + 1/EA	Smiths Medical ASD, Inc. 5700 West 23 rd Avenue, Gary, IN 46406 USA	N/A	63798	I Ib	5
144.	75FHXL80	8.0 MM XL FIXED HYPERFLEX MR AC + 1/EA	Smiths Medical ASD, Inc. 5700 West 23 rd Avenue, Gary, IN 46406 USA	N/A	63798	I Ib	5
145.	75FHXL90	9.0 MM XL FIXED HYPERFLEX MR AC + 1/EA	Smiths Medical ASD, Inc. 5700 West 23 rd Avenue, Gary, IN 46406 USA	N/A	63798	I Ib	5
146.	75HA60	AIRE-CUF TRACHY TUBE 6.0MM ADLT MID-RNGE,ADJUST HYPERFLEX 1/EA	Smiths Medical ASD, Inc. 5700 West 23 rd Avenue, Gary, IN 46406 USA	N/A	63798	I Ia	5
147.	75HA70	AIRE-CUF TRACHY TUBE 7.0MM ADLT MID-RNGE,ADJUST HYPERFLEX 1/EA	Smiths Medical ASD, Inc. 5700 West 23 rd Avenue, Gary, IN 46406 USA	N/A	63798	I Ia	5
148.	75HA80	AIRE-CUF TRACHY TUBE 8.0MM ADLT MID-RNGE,ADJUST HYPERFLEX 1/EA	Smiths Medical ASD, Inc. 5700 West 23 rd Avenue, Gary, IN 46406 USA	N/A	63798	I Ia	5

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149.	75HA90	AIRE-CUF TRACHY TUBE 9.0MM ADLT MID-RNGE,ADJUST HYPERFLEX 1/EA	Smiths Medical ASD, Inc. 5700 West 23 rd Avenue, Gary, IN 46406 USA	N/A	63798	Ila	5
150.	850150	FOME CUF TRACH TUBE 5.0 + 1/EA	Smiths Medical ASD, Inc. 5700 West 23 rd Avenue, Gary, IN 46406 USA	N/A	63798	IIb	5
151.	850160	FOME CUF TRACH TUBE 6.0 + 1/EA	Smiths Medical ASD, Inc. 5700 West 23 rd Avenue, Gary, IN 46406 USA	N/A	63798	IIb	5
152.	850170	FOME CUF TRACH TUBE 7.0 + 1/EA	Smiths Medical ASD, Inc. 5700 West 23 rd Avenue, Gary, IN 46406 USA	N/A	63798	IIb	5
153.	850180	FOME-CUF TRACH TUBE 8.0 + 1/EA	Smiths Medical ASD, Inc. 5700 West 23 rd Avenue, Gary, IN 46406 USA	N/A	63798	IIb	5
154.	850190	FOME-CUF TRACH TUBE 9.0 + 1/EA	Smiths Medical ASD, Inc. 5700 West 23 rd Avenue, Gary, IN 46406 USA	N/A	63798	IIb	5
155.	850195	FOME-CUF TRACH TUBE 9.5 + 1/EA	Smiths Medical ASD, Inc. 5700 West 23 rd Avenue, Gary, IN 46406 USA	N/A	63798	IIb	5
156.	855150	FOME CUF TRACH W/TALK + 1/EA	Smiths Medical ASD, Inc. 5700 West 23 rd Avenue, Gary, IN 46406 USA	N/A	63798	IIb	5
157.	855160	FOME CUF TRACH W/TALK + 1/EA	Smiths Medical ASD, Inc. 5700 West 23 rd Avenue, Gary, IN 46406 USA	N/A	63798	IIb	5
158.	855170	FOME CUF TRACH W/TALK + 1/EA	Smiths Medical ASD, Inc. 5700 West 23 rd Avenue, Gary, IN 46406 USA	N/A	63798	IIb	5
159.	855180	FOME CUF TRACH W/TALK + 1/EA	Smiths Medical ASD, Inc. 5700 West 23 rd Avenue, Gary, IN 46406 USA	N/A	63798	IIb	5
160.	855190	FOME CUF TRACH W/TALK + 1/EA	Smiths Medical ASD, Inc. 5700 West 23 rd Avenue, Gary, IN 46406 USA	N/A	63798	IIb	5

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161.	85N030	NEONATAL TRACHEOSTOMY TUBE 3.0FOME-CUF, TRACHEOSTOMA SEAL 1/EA	Smiths Medical ASD, Inc. 5700 West 23 rd Avenue, Gary, IN 46406 USA	N/A	63798	Ilb	5
162.	85N035	NEONATAL TRACHEOSTOMY TUBE 3.5FOME-CUF, TRACHEOSTOMA SEAL 1/EA	Smiths Medical ASD, Inc. 5700 West 23 rd Avenue, Gary, IN 46406 USA	N/A	63798	Ilb	5
163.	85N040	NEONATAL TRACHEOSTOMY TUBE 4.0FOME-CUF, TRACHEOSTOMA SEAL 1/EA	Smiths Medical ASD, Inc. 5700 West 23 rd Avenue, Gary, IN 46406 USA	N/A	63798	Ilb	5
164.	85P025	PAED. TRACHEOSTOMY TUBE 2.5MM FOME-CUF, TRACHEOSTOMA SEAL 1/EA	Smiths Medical ASD, Inc. 5700 West 23 rd Avenue, Gary, IN 46406 USA	N/A	63798	Ilb	5
165.	85P030	PAED. TRACHEOSTOMY TUBE 3.0MM FOME-CUF, TRACHEOSTOMA SEAL 1/EA	Smiths Medical ASD, Inc. 5700 West 23 rd Avenue, Gary, IN 46406 USA	N/A	63798	Ilb	5
166.	85P035	PAED. TRACHEOSTOMY TUBE 3.5MM FOME-CUF, TRACHEOSTOMA SEAL 1/EA	Smiths Medical ASD, Inc. 5700 West 23 rd Avenue, Gary, IN 46406 USA	N/A	63798	Ilb	5
167.	85P040	PAED. TRACHEOSTOMY TUBE 4.0MM FOME-CUF, TRACHEOSTOMA SEAL 1/EA	Smiths Medical ASD, Inc. 5700 West 23 rd Avenue, Gary, IN 46406 USA	N/A	63798	Ilb	5
168.	85P045	PAED. TRACHEOSTOMY TUBE 4.5MM FOME-CUF, TRACHEOSTOMA SEAL 1/EA	Smiths Medical ASD, Inc. 5700 West 23 rd Avenue, Gary, IN 46406 USA	N/A	63798	Ilb	5
169.	85P050	PAED. TRACHEOSTOMY TUBE 5.0MM FOME-CUF, TRACHEOSTOMA SEAL 1/EA	Smiths Medical ASD, Inc. 5700 West 23 rd Avenue, Gary, IN 46406 USA	N/A	63798	Ilb	5
170.	85P055	PAED. TRACHEOSTOMY TUBE 5.5MM FOME-CUF, TRACHEOSTOMA SEAL 1/EA	Smiths Medical ASD, Inc. 5700 West 23 rd Avenue, Gary, IN 46406 USA	N/A	63798	Ilb	5
171.	60P025	PAED. TRACHEOSTOMY TUBE 2.5MM UNCUFFED 1/EA	Smiths Medical ASD, Inc. 5700 West 23 rd Avenue, Gary, IN 46406 USA	N/A	38792	Ilb	5
172.	60P030	PAED. TRACHEOSTOMY TUBE 3.0MM UNCUFFED 1/EA	Smiths Medical ASD, Inc. 5700 West 23 rd Avenue, Gary, IN 46406 USA	N/A	38792	Ilb	5

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173.	60P035	PAED. TRACHEOSTOMY TUBE 3.5MM UNCUFFED 1/EA	Smiths Medical ASD, Inc. 5700 West 23 rd Avenue, Gary, IN 46406 USA	N/A	38792	Ilb	5
174.	60P040	PAED. TRACHEOSTOMY TUBE 4.0MM UNCUFFED 1/EA	Smiths Medical ASD, Inc. 5700 West 23 rd Avenue, Gary, IN 46406 USA	N/A	38792	Ilb	5
175.	60P045	PAED. TRACHEOSTOMY TUBE 4.5MM UNCUFFED 1/EA	Smiths Medical ASD, Inc. 5700 West 23 rd Avenue, Gary, IN 46406 USA	N/A	38792	Ilb	5
176.	60P050	PAED. TRACHEOSTOMY TUBE 5.0MM UNCUFFED 1/EA	Smiths Medical ASD, Inc. 5700 West 23 rd Avenue, Gary, IN 46406 USA	N/A	38792	Ilb	5
177.	60P055	PAED. TRACHEOSTOMY TUBE 5.5MM UNCUFFED 1/EA	Smiths Medical ASD, Inc. 5700 West 23 rd Avenue, Gary, IN 46406 USA	N/A	38792	Ilb	5
178.	67NFPS25	NEONATAL TRACHEOSTOMY TUBE 2.5 TTS FLEXTEND STRAIGHT FLANGE 1/EA	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	N/A	63798	Ilb	5
179.	67NFPS30	NEONATAL TRACHEOSTOMY TUBE 3.0 TTS FLEXTEND STRAIGHT FLANGE 1/EA	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	N/A	63798	Ilb	5
180.	67NFPS35	NEONATAL TRACHEOSTOMY TUBE 3.5 TTS FLEXTEND STRAIGHT FLANGE 1/EA	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	N/A	63798	Ilb	5
181.	67NFPS40	NEONATAL TRACHEOSTOMY TUBE 4.0 TTS FLEXTEND STRAIGHT FLANGE 1/EA	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	N/A	63798	Ilb	5

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Num	Catalog Number	Product Description	Manufacturing Site	UMDNS (if applicable)	GMDN Code	EU Risk Class	EU Rule
182.	67NFP25	NEONATAL TRACHEOSTOMY TUBE 2.5 TTS FLEXTEND V FLANGE 1/EA	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	N/A	63798	IIb	5
183.	67NFP30	NEONATAL TRACHEOSTOMY TUBE 3.0 TTS FLEXTEND V FLANGE 1/EA	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	N/A	63798	IIb	5
184.	67NFP35	NEONATAL TRACHEOSTOMY TUBE 3.5 TTS FLEXTEND V FLANGE 1/EA	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	N/A	63798	IIb	5
185.	67NFP40	NEONATAL TRACHEOSTOMY TUBE 4.0 TTS FLEXTEND V FLANGE 1/EA	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	N/A	63798	IIb	5
186.	67PFSS25	PEDIATRIC TRACHEOSTOMY TUBE 2.5 TTS FLEXTEND STRAIGHT NECK 1/EA	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	N/A	63798	IIb	5
187.	67PFSS30	PEDIATRIC TRACHEOSTOMY TUBE 3.0 TTS FLEXTEND STRAIGHT NECK 1/EA	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	N/A	63798	IIb	5
188.	67PFSS35	PEDIATRIC TRACHEOSTOMY TUBE 3.5 TTS FLEXTEND STRAIGHT NECK 1/EA	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	N/A	63798	IIb	5

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Num	Catalog Number	Product Description	Manufacturing Site	UMDNS (if applicable)	GMDN Code	EU Risk Class	EU Rule
189.	67PFSS40	PEDIATRIC TRACHEOSTOMY TUBE 4.0 TTS FLEXTEND STRAIGHT NECK 1/EA	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	N/A	63798	Ilb	5
190.	67PFSS45	PEDIATRIC TRACHEOSTOMY TUBE 4.5 TTS FLEXTEND STRAIGHT NECK 1/EA	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	N/A	63798	Ilb	5
191.	67PFSS50	PEDIATRIC TRACHEOSTOMY TUBE 5.0 TTS FLEXTEND STRAIGHT NECK 1/EA	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	N/A	63798	Ilb	5
192.	67PFSS55	PEDIATRIC TRACHEOSTOMY TUBE 5.5 TTS FLEXTEND STRAIGHT NECK 1/EA	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	N/A	63798	Ilb	5
193.	67PFPS40	PEDIATRIC TRACHEOSTOMY TUBE 4.0 TTS FLEXTEND PLUS STRAIGHT FLANGE 1/EA	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	N/A	63798	Ilb	5
194.	67PFPS45	PEDIATRIC TRACHEOSTOMY TUBE 4.5 TTS FLEXTEND PLUS STRAIGHT FLANGE 1/EA	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	N/A	63798	Ilb	5
195.	67PFPS50	PEDIATRIC TRACHEOSTOMY TUBE 5.0 TTS FLEXTEND PLUS STRAIGHT FLANGE 1/EA	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	N/A	63798	Ilb	5

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Num	Catalog Number	Product Description	Manufacturing Site	UMDNS (if applicable)	GMDN Code	EU Risk Class	EU Rule
196.	67PFPS55	PEDIATRIC TRACHEOSTOMY TUBE 5.5 TTS FLEXTEND PLUS STRAIGHT FLANGE 1/EA	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	N/A	63798	IIb	5
197.	67PFPS60	PEDIATRIC TRACHEOSTOMY TUBE 6.0 TTS FLEXTEND PLUS STRAIGHT FLANGE 1/EA	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	N/A	63798	IIb	5
198.	67PFS25	PEDIATRIC TRACHEOSTOMY TUBE 2.5 TTS FLEXTEND V NECK 1/EA	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	N/A	63798	IIb	5
199.	67PFS30	PEDIATRIC TRACHEOSTOMY TUBE 3.0 TTS FLEXTEND V NECK 1/EA	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	N/A	63798	IIb	5
200.	67PFS35	PEDIATRIC TRACHEOSTOMY TUBE 3.5 TTS FLEXTEND V NECK 1/EA	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	N/A	63798	IIb	5
201.	67PFS40	PEDIATRIC TRACHEOSTOMY TUBE 4.0 TTS FLEXTEND V NECK 1/EA	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	N/A	63798	IIb	5
202.	67PFS45	PEDIATRIC TRACHEOSTOMY TUBE 4.5 TTS FLEXTEND V NECK 1/EA	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	N/A	63798	IIb	5

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Num	Catalog Number	Product Description	Manufacturing Site	UMDNS (if applicable)	GMDN Code	EU Risk Class	EU Rule
203.	67PFS50	PEDIATRIC TRACHEOSTOMY TUBE 5.0 TTS FLEXTEND V NECK 1/EA	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	N/A	63798	IIb	5
204.	67PFS55	PEDIATRIC TRACHEOSTOMY TUBE 5.5 TTS FLEXTEND V NECK 1/EA	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	N/A	63798	IIb	5
205.	67PFP40	PEDIATRIC TRACHEOSTOMY TUBE 4.0 TTS FLEXTEND PLUS V FLANGE 1/EA	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	N/A	63798	IIb	5
206.	67PFP45	PEDIATRIC TRACHEOSTOMY TUBE 4.5 TTS FLEXTEND PLUS V FLANGE 1/EA	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	N/A	63798	IIb	5
207.	67PFP50	PEDIATRIC TRACHEOSTOMY TUBE 5.0 TTS FLEXTEND PLUS V FLANGE 1/EA	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	N/A	63798	IIb	5
208.	67PFP55	PEDIATRIC TRACHEOSTOMY TUBE 5.5 TTS FLEXTEND PLUS V FLANGE 1/EA	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	N/A	63798	IIb	5
209.	67PFP60	PEDIATRIC TRACHEOSTOMY TUBE 6.0 TTS FLEXTEND PLUS V FLANGE 1/EA	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	N/A	63798	IIb	5
210.	AUXXXXXXXXXXXXXX	Uncuffed Adjustable Hyperflex	Smiths Medical ASD, Inc. 5700 West 23 rd Avenue, Gary, IN 46406 USA	N/A	47657	IIb	5

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Num	Catalog Number	Product Description	Manufacturing Site	UMDNS (if applicable)	GMDN Code	EU Risk Class	EU Rule
211.	AAXXXXXXXXXXXXXX	Adjustable Hyperflex® with an Adult Aire-Cuff®	Smiths Medical ASD, Inc. 5700 West 23 rd Avenue, Gary, IN 46406 USA	N/A	47657	IIb	5
212.	ATXXXXXXXXXXXXXX	Adjustable Hyperflex® with a TTS™ Cuff	Smiths Medical ASD, Inc. 5700 West 23 rd Avenue, Gary, IN 46406 USA	N/A	47657	IIb	5
213.	AFXXXXXXXXXXXXXX	Adjustable Hyperflex® with a Fome-Cuff®	Smiths Medical ASD, Inc. 5700 West 23 rd Avenue, Gary, IN 46406 USA	N/A	47657	IIb	5
214.	APXXXXXXXXXXXXXX	Adjustable Hyperflex® with a Pedi Aire-Cuff®	Smiths Medical ASD, Inc. 5700 West 23 rd Avenue, Gary, IN 46406 USA	N/A	47657	IIb	5
215.	AZXXXXXXXXXXXXXX	Adjustable Hyperflex® with a Customized Primary Cuff	Smiths Medical ASD, Inc. 5700 West 23 rd Avenue, Gary, IN 46406 USA	N/A	63060	IIb	5
216.	SUXXXXXXXXXXXXXX	Uncuffed Standard Fixed	Smiths Medical ASD, Inc. 5700 West 23 rd Avenue, Gary, IN 46406 USA	N/A	63798	IIb	5
217.	SAXXXXXXXXXXXXXX	Standard Fixed with an Adult Aire-Cuff®	Smiths Medical ASD, Inc. 5700 West 23 rd Avenue, Gary, IN 46406 USA	N/A	38792	IIb	5
218.	STXXXXXXXXXXXXXX	Standard Fixed with a TTS™ Cuff	Smiths Medical ASD, Inc. 5700 West 23 rd Avenue, Gary, IN 46406 USA	N/A	38792	IIb	5
219.	SFXXXXXXXXXXXXXX	Standard Fixed with a Fome-Cuff®	Smiths Medical ASD, Inc. 5700 West 23 rd Avenue, Gary, IN 46406 USA	N/A	63798	IIb	5
220.	SPXXXXXXXXXXXXXX	Standard Fixed with a Pedi Aire-Cuff®	Smiths Medical ASD, Inc. 5700 West 23 rd Avenue, Gary, IN 46406 USA	N/A	63798	IIb	5
221.	SZXXXXXXXXXXXXXX	Standard Fixed with a Customized Primary Cuff	Smiths Medical ASD, Inc. 5700 West 23 rd Avenue, Gary, IN 46406 USA	N/A	63060	IIb	5
222.	HUXXXXXXXXXXXXXX	Uncuffed Fixed Hyperflex®	Smiths Medical ASD, Inc. 5700 West 23 rd Avenue, Gary, IN 46406 USA	N/A	63798	IIb	5

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Num	Catalog Number	Product Description	Manufacturing Site	UMDNS (if applicable)	GMDN Code	EU Risk Class	EU Rule
223.	HAXXXXXXXXXXXXXX	Fixed Hyperflex® with an Adult Aire-Cuff®	Smiths Medical ASD, Inc. 5700 West 23 rd Avenue, Gary, IN 46406 USA	N/A	63798	IIb	5
224.	HTXXXXXXXXXXXXXX	Fixed Hyperflex® with a TTS™ Cuff	Smiths Medical ASD, Inc. 5700 West 23 rd Avenue, Gary, IN 46406 USA	N/A	63798	IIb	5
225.	HFXXXXXXXXXXXXXX	Fixed Hyperflex® with a Fome-Cuff®	Smiths Medical ASD, Inc. 5700 West 23 rd Avenue, Gary, IN 46406 USA	N/A	63798	IIb	5
226.	HPXXXXXXXXXXXXXX	Fixed Hyperflex® with a Pedi Aire-Cuff®	Smiths Medical ASD, Inc. 5700 West 23 rd Avenue, Gary, IN 46406 USA	N/A	63798	IIb	5
227.	HZXXXXXXXXXXXXXX	Fixed Hyperflex® with a Customized Primary Cuff	Smiths Medical ASD, Inc. 5700 West 23 rd Avenue, Gary, IN 46406 USA	N/A	63060	IIb	5
228.	FUXXXXXXXXXXXXXX	Uncuffed FlexTend™ Standard	Smiths Medical ASD, Inc. 5700 West 23 rd Avenue, Gary, IN 46406 USA	N/A	63798	IIb	5
229.	FAXXXXXXXXXXXXXX	FlexTend™ Standard with an Adult Aire-Cuff®	Smiths Medical ASD, Inc. 5700 West 23 rd Avenue, Gary, IN 46406 USA	N/A	63798	IIb	5
230.	FTXXXXXXXXXXXXXX	FlexTend™ Standard with a TTS™ Cuff	Smiths Medical ASD, Inc. 5700 West 23 rd Avenue, Gary, IN 46406 USA	N/A	63798	IIb	5
231.	FFXXXXXXXXXXXXXX	FlexTend™ Standard with a Fome-Cuff®	Smiths Medical ASD, Inc. 5700 West 23 rd Avenue, Gary, IN 46406 USA	N/A	63798	IIb	5
232.	FPXXXXXXXXXXXXXX	FlexTend™ Standard with a Pedi Aire-Cuff®	Smiths Medical ASD, Inc. 5700 West 23 rd Avenue, Gary, IN 46406 USA	N/A	63798	IIb	5
233.	FZXXXXXXXXXXXXXX	FlexTend™ Standard with a Customized Primary Cuff	Smiths Medical ASD, Inc. 5700 West 23 rd Avenue, Gary, IN 46406 USA	N/A	63060	IIb	5
234.	XUXXXXXXXXXXXXXX	Uncuffed FlexTend Hyperflex®	Smiths Medical ASD, Inc. 5700 West 23 rd Avenue, Gary, IN 46406 USA	N/A	63798	IIb	5

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Num	Catalog Number	Product Description	Manufacturing Site	UMDNS (if applicable)	GMDN Code	EU Risk Class	EU Rule
235.	XAXXXXXXXXXXXXXX	FlexTend™ Hyperflex® with an Adult Aire-Cuff®	Smiths Medical ASD, Inc. 5700 West 23 rd Avenue, Gary, IN 46406 USA	N/A	63798	I Ib	5
236.	XTXXXXXXXXXXXXX	FlexTend™ Hyperflex® with a TTS™ Cuff	Smiths Medical ASD, Inc. 5700 West 23 rd Avenue, Gary, IN 46406 USA	N/A	63798	I Ib	5
237.	XFXXXXXXXXXXXXX	FlexTend™ Hyperflex® with a Fome-Cuff®	Smiths Medical ASD, Inc. 5700 West 23 rd Avenue, Gary, IN 46406 USA	N/A	63798	I Ib	5
238.	XPXXXXXXXXXXXXX	FlexTend™ Hyperflex® with a Pedi Aire-Cuff®	Smiths Medical ASD, Inc. 5700 West 23 rd Avenue, Gary, IN 46406 USA	N/A	63798	I Ib	5
239.	XZXXXXXXXXXXXXX	Bivona® with a Customized Primary Cuff	Smiths Medical ASD, Inc. 5700 West 23 rd Avenue, Gary, IN 46406 USA	N/A	63060	I Ib	5
240.	ZUXXXXXXXXXXXXX	Uncuffed Bivona® Customized	Smiths Medical ASD, Inc. 5700 West 23 rd Avenue, Gary, IN 46406 USA	N/A	63060	I Ib	5
241.	ZAXXXXXXXXXXXXXX	Bivona® Customized with an Adult Aire-Cuf®	Smiths Medical ASD, Inc. 5700 West 23 rd Avenue, Gary, IN 46406 USA	N/A	63060	I Ib	5
242.	ZTXXXXXXXXXXXXX	Bivona® Customized with a TTS™ Cuff	Smiths Medical ASD, Inc. 5700 West 23 rd Avenue, Gary, IN 46406 USA	N/A	63060	I Ib	5
243.	ZFXXXXXXXXXXXXX	Bivona® Customized with a Fome-Cuff®	Smiths Medical ASD, Inc. 5700 West 23 rd Avenue, Gary, IN 46406 USA	N/A	63060	I Ib	5
244.	ZPXXXXXXXXXXXXX	Bivona® Customized with a Pedi Aire-Cuff®	Smiths Medical ASD, Inc. 5700 West 23 rd Avenue, Gary, IN 46406 USA	N/A	63060	I Ib	5
245.	ZZXXXXXXXXXXXXX	Bivona® Customized with a Customized Primary Cuff	Smiths Medical ASD, Inc. 5700 West 23 rd Avenue, Gary, IN 46406 USA	N/A	63060	I Ib	5
246.	BOSL1L	BIVONA LARYNGECTOMY TUBE NS + 1/EA	Smiths Medical ASD, Inc. 5700 West 23 rd Avenue, Gary, IN 46406 USA	N/A	12292	I Ib	5

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Num	Catalog Number	Product Description	Manufacturing Site	UMDNS (if applicable)	GMDN Code	EU Risk Class	EU Rule
247.	BOSL3L	BIVONA LARYNGECTOMY TUBE NS + 1/EA	Smiths Medical ASD, Inc. 5700 West 23 rd Avenue, Gary, IN 46406 USA	N/A	12292	I Ib	5
248.	BOSL3S	BIVONA LARYNGECTOMY TUBE NS + 1/EA	Smiths Medical ASD, Inc. 5700 West 23 rd Avenue, Gary, IN 46406 USA	N/A	12292	I Ib	5
249.	BOSL5L	BIVONA LARYNGECTOMY TUBE NS + 1/EA	Smiths Medical ASD, Inc. 5700 West 23 rd Avenue, Gary, IN 46406 USA	N/A	12292	I Ib	5
250.	BOSL5S	BIVONA LARYNGECTOMY TUBE NS + 1/EA	Smiths Medical ASD, Inc. 5700 West 23 rd Avenue, Gary, IN 46406 USA	N/A	12292	I Ib	5

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Appendix 2: Revision History

Revision Number	Summary of Changes / Additions	Created / Revised by	Date (DD-MMM-YYYY Format)
002	Last DoC Release	Jim Broughton	03-AUG-15
003	Update format due to DVDP1509-01 Rev 001 Remove R67N0xx and R67P0xx because OBS Separate Table for Laryngectomy Tubes	Donna M. Semlak	12-AUG-16
004	Change Manufacturing Site, moved to TIJ site, refer to CR-10003139; Updating to the new template	Mitchell Madsen	12-JAN-2017
005	Change document number format from SXXX to DoC-XXX to load documents into Agile. No updates made to content of this document with the exception of the document number from S1188 to DoC-137 and revision from 004 to 005 and added STED # to header for traceability to STED.	Stacy Novak	30-MAY-2017
006	Removed Notified Body address for consistency across all DoCs	Stacy Novak	05-JUN-2017
007	Updating CE Cert number from 551 CE to 551-01 CE and updating Issued By date from 15 Jan 2014 to 15JUL2017. Correct customized part numbers to 15 digits and add "Z" Customized Tier 1 options (Device Type and Cuff)	Mitchell Madsen	11-AUG-2017
008	Updated the DoC to the latest template in Agile from Rev 002 to 003. Updated the Certificate Number from 551-01 CE to 551-02 CE due to the certificate expiring.	Mitchell Madsen	07-MAR-2018
009	Made an administrative change to correct crossed out date on previous revision.	Mitchell Madsen	02-APR-2018
136	- Revisions should begin with 100 at production lifecycle status, per DVSOP2005. - Aligning Revisions of DOC, ERC and STED to same revision. - Administrative update due to Intertek AMTAC (0473) closing its offices effective 30-JUN-2018. Therefore, Smiths Medical transferred from Intertek AMTAC #0473 to Intertek SEMKO AB #0413 effective 1-July-2018. - Changed the Authorized Signatory from Stacy Novak to Donna Semlak for Regulatory Affairs approval.	Kristen Evenson	04-SEP-2018

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137	- Update for 1 piece revision of EU STED S1188. - Update GMDN codes to 63793 for Hyperflex and FlexTend tubes with fixed flanges, as these are reinforced tracheostomy tubes that are reusable.	Kristen Evenson	22-OCT-2018
138	DOC update corresponds to STED updates for Installation and validation of a new a new Ethylene Oxide (EO) sterilizer in Southington, CT; for custom-made and customized tracheostomy tubes and updated Packaging Reports.	Kristen Evenson	29-MAR-2019
139	-Updated the DoC to the latest template in Agile from Rev 003 to 104. - Changed the legal manufacturer from MHYT to MMSP as per FM-DVSOP8005-05 -Updated the STED Name on the DoC from Bivona Tracheostomy and Laryngectomy Tubes to Tracheostomy and Laryngectomy Tubes to match the STED Name in Agile. - 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 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. - Changed the Notified Body from Intertek SEMKO to BSI and the EC Certificate from 41377460-00 to CE 669121 as the Notified Body for the SKUs on this DoC has changed from SEMKO to BSI. - Changed the Product Scope from "Tracheostomy Tubes" to "Sterile Tracheostomy Tubes and Kits" to align with Product Scope on EC Certificate 669121. -Updated the Start of CE Marking date from 15 July 2002 to JUL, 2002.	Mitchell Madsen	08-AUG-2019

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Revision Number	Summary of Changes / Additions	Created / Revised by	Date (DD-MMM-YYYY Format)
	-Changed the Product Descriptions for the Catalog Numbers in Appendix 1 to match their Agile Descriptions. -Updated the Gary address in the Manufacturing Site column in Appendix 1 to match the address in EC Certificate 669121. -Updated the Tijuana address in the Manufacturing Site column in Appendix 1 to match the address in EC Certificate 669121. -Removed the following SKUs from DoC-137 due to being in the Service lifecycle phase and do not belong on a DoC: R60N025, R60N030, R60N040. -Removed the following SKUs from DoC-137 due to being in the Obsolete lifecycle phase and do not belong on a DoC: R60N035, BOSL1S. -Added the following SKUs to DoC-137 due to having sales in the EU and needing to be covered by a DoC: ATXXXXXXXXXXXXX, AFXXXXXXXXXXXXX, AZXXXXXXXXXXXXX, SZXXXXXXXXXXXXX, HZXXXXXXXXXXXXX, FZXXXXXXXXXXXXX, ZUXXXXXXXXXXXXX, ZAXXXXXXXXXXXXXX, ZTXXXXXXXXXXXXX, ZFXXXXXXXXXXXXX, ZPXXXXXXXXXXXXX. -Changed the GMDN Code from 38792 to 63798 for the following SKUs to better align the GMDN Code to the products: 60AFHXL60, 60AFHXL70, 60AFHXL80, 60AFHXL90, 60N025, 60N030, 60N035, 60N040, 60NFP25, 60NFP30, 60NFP35, 60NFP40, 60NFPS25, 60NFPS30, 60NFPS35, 60NFPS40, 60PFP40, 60PFP45, 60PFP50, 60PFP55, 60PFP60, 60PFPS40, 60PFPS45, 60PFPS50, 60PFPS55, 60PFPS60, 60PFS25, 60PFS30, 60PFS35, 60PFS40, 60PFS45, 60PFS50, 60PFS55, 60PFSS25, 60PFSS30, 60PFSS35, 60PFSS40, 60PFSS45, 60PFSS50, 60PFSS55, 60SN025, 60SN030, 60SN035, 60SN040, 65N025, 65N030, 65N035, 65N040, 65P025, 65P030, 65P035, 65P040, 65P045, 65P050, 65P055, 65SN025, 65SN030, 65SN035, 65SN040, 65SP025, 65SP030,		

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Revision Number	Summary of Changes / Additions	Created / Revised by	Date (DD-MMM-YYYY Format)
	65SP035, 65SP040, 65SP045, 65SP050, 65SP055, 67FHXL60, 67FHXL70, 67FHXL80, 67FHXL90, 67N025, 67N030, 67N035, 67N040, 67SN025, 67SN030, 67SN035, 67SN040, 75FHXL60, 75FHXL70, 75FHXL80, 75FHXL90, 850150, 850160, 850170, 850180, 850190, 850195, 855150, 855160, 855170, 855180, 855190, 85N030, 85N035, 85N040, 85P025, 85P030, 85P035, 85P040, 85P045, 85P050, 85P055, R60N025, R60N030, R60N035, R60N040, 67NFPS25, 67NFPS30, 67NFPS35, 67NFPS40, 67NFP25, 67NFP30, 67NFP35, 67NFP40, 67PFSS25, 67PFSS30, 67PFSS35, 67PFSS40, 67PFSS45, 67PFSS50, 67PFSS55, 67PFPS40, 67PFPS45, 67PFPS50, 67PFPS55, 67PFPS60, 67PFS25, 67PFS30, 67PFS35, 67PFS40, 67PFS45, 67PFS50, 67PFS55, 67PFP40, 67PFP45, 67PFP50, 67PFP55, 67PFP60, SUXXXXXXXXXXXXXX, SFXXXXXXXXXXXXXX, SPXXXXXXXXXXXXXX, HUXXXXXXXXXXXXXX, HAXXXXXXXXXXXXXX, HTXXXXXXXXXXXXXX, HFXXXXXXXXXXXXXX, HPXXXXXXXXXXXXXX, FUXXXXXXXXXXXXXX, FAXXXXXXXXXXXXXX, FTXXXXXXXXXXXXXX, FFXXXXXXXXXXXXXX, FPXXXXXXXXXXXXXX, XUXXXXXXXXXXXXXX, XAXXXXXXXXXXXXXX, XTXXXXXXXXXXXXXX, XFXXXXXXXXXXXXXX, XPXXXXXXXXXXXXXX		
140	Changed the GMDN Code for 75HA60, 75HA70, 75HA80, and 75HA90 from 63793 to 63798 as 63793 is not a valid GMDN Code. 63798 is valid and applicable.	Alicia Wilson	22-AUG-2019