

	Declaration of Conformity	DoC-034 Revision Number: 110
	S1028: Intubation and Endotracheal 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): 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
Medical Devices Certification
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: 07 AUG 2019

Name: Stacy Novak

Title: Sr. Manager, Regulatory Operations

Location of Signatory: Minneapolis, MN, USA

 bringing technology to life	Declaration of Conformity		DoC-034
	S1028: Intubation and Endotracheal Tubes		Revision Number: 110

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	Ila	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	Ila	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	Ila	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	Ila	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	Ila	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	Ila	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	Ila	5

 bringing technology to life	Declaration of Conformity		DoC-034
	S1028: Intubation and Endotracheal Tubes		Revision Number: 110

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	Ila	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	Ila	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	Ila	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	Ila	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	Ila	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	Ila	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	Ila	5

 bringing technology to life	Declaration of Conformity		DoC-034
	S1028: Intubation and Endotracheal Tubes		Revision Number: 110

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	Ila	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	Ila	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	Ila	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	Ila	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	Ila	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	Ila	5

 bringing technology to life	Declaration of Conformity		DoC-034
	S1028: Intubation and Endotracheal Tubes		Revision Number: 110

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	Ila	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	Ila	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	Ila	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	Ila	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	Ila	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	Ila	5

 bringing technology to life	Declaration of Conformity	DoC-034 Revision Number: 110
	S1028: Intubation and Endotracheal Tubes	

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	Ila	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	Ila	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	Ila	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	Ila	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	Ila	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	Ila	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	Ila	5

 bringing technology to life	Declaration of Conformity	DoC-034
	S1028: Intubation and Endotracheal Tubes	Revision Number: 110

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	Ila	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	Ila	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	Ila	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	Ila	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	Ila	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	Ila	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	Ila	5

 bringing technology to life	Declaration of Conformity		DoC-034
	S1028: Intubation and Endotracheal Tubes		Revision Number: 110

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	Ila	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	Ila	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	Ila	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	Ila	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	Ila	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	Ila	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	Ila	5

 bringing technology to life	Declaration of Conformity		DoC-034 Revision Number: 110
	S1028: Intubation and Endotracheal Tubes		

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	Ila	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	Ila	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	Ila	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	Ila	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	Ila	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	Ila	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	Ila	5

 bringing technology to life	Declaration of Conformity		DoC-034
	S1028: Intubation and Endotracheal Tubes		Revision Number: 110

Num	Catalog Number	Product Description	Manufacturing Site	UMDNS (if applicable)	GMDN Code	EU Risk Class	EU Rule
55.	100/112/045	Tracheal Tube Paed Group 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	Ila	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	Ila	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	Ila	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	Ila	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	Ila	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	Ila	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	Ila	5

 bringing technology to life	Declaration of Conformity		DoC-034
	S1028: Intubation and Endotracheal Tubes		Revision Number: 110

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	Ila	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	Ila	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	Ila	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	Ila	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	Ila	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	Ila	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	Ila	5

 bringing technology to life	Declaration of Conformity		DoC-034
	S1028: Intubation and Endotracheal Tubes		Revision Number: 110

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	Ila	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	Ila	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	Ila	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	Ila	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	Ila	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	Ila	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	Ila	5

 bringing technology to life	Declaration of Conformity		DoC-034
	S1028: Intubation and Endotracheal Tubes		Revision Number: 110

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	Ila	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	Ila	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	Ila	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	Ila	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	Ila	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	Ila	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	Ila	5

 bringing technology to life	Declaration of Conformity		DoC-034
	S1028: Intubation and Endotracheal Tubes		Revision Number: 110

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	Ila	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	Ila	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	Ila	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	Ila	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	Ila	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	Ila	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	Ila	5

 bringing technology to life	Declaration of Conformity		DoC-034 Revision Number: 110
	S1028: Intubation and Endotracheal Tubes		

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	Ila	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	Ila	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	Ila	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	Ila	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	Ila	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	Ila	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	Ila	5

 bringing technology to life	Declaration of Conformity		DoC-034 Revision Number: 110
	S1028: Intubation and Endotracheal Tubes		

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	Ila	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	Ila	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	Ila	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	Ila	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	Ila	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	Ila	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	Ila	5

 bringing technology to life	Declaration of Conformity		DoC-034
	S1028: Intubation and Endotracheal Tubes		Revision Number: 110

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	Ila	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	Ila	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	Ila	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	Ila	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	Ila	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	Ila	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	Ila	5

 bringing technology to life	Declaration of Conformity		DoC-034 Revision Number: 110
	S1028: Intubation and Endotracheal Tubes		

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	Ila	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	Ila	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	Ila	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	Ila	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	Ila	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	Ila	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	Ila	5

 bringing technology to life	Declaration of Conformity		DoC-034
	S1028: Intubation and Endotracheal Tubes		Revision Number: 110

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	Ila	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	Ila	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	Ila	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	Ila	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	Ila	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	Ila	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	Ila	5

 bringing technology to life	Declaration of Conformity	DoC-034
	S1028: Intubation and Endotracheal Tubes	Revision Number: 110

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	Ila	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	Ila	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	Ila	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	Ila	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	Ila	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	Ila	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	Ila	5

 bringing technology to life	Declaration of Conformity		DoC-034
	S1028: Intubation and Endotracheal Tubes		Revision Number: 110

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	Ila	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	Ila	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	Ila	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	Ila	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	Ila	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	Ila	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	Ila	5

 bringing technology to life	Declaration of Conformity		DoC-034
	S1028: Intubation and Endotracheal Tubes		Revision Number: 110

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	Ila	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	Ila	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	Ila	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	Ila	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	Ila	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	Ila	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	Ila	5

 bringing technology to life	Declaration of Conformity		DoC-034
	S1028: Intubation and Endotracheal Tubes		Revision Number: 110

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	Ila	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	Ila	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	Ila	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	Ila	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	Ila	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	Ila	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	Ila	5

 bringing technology to life	Declaration of Conformity		DoC-034
	S1028: Intubation and Endotracheal Tubes		Revision Number: 110

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	Ila	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	Ila	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	Ila	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	Ila	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	Ila	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	Ila	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	Ila	5

 bringing technology to life	Declaration of Conformity		DoC-034
	S1028: Intubation and Endotracheal Tubes		Revision Number: 110

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	Ila	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	Ila	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	Ila	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	Ila	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	Ila	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	Ila	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	Ila	5

 bringing technology to life	Declaration of Conformity		DoC-034
	S1028: Intubation and Endotracheal Tubes		Revision Number: 110

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	Ila	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	Ila	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	Ila	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	Ila	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	Ila	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	Ila	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	Ila	5

 bringing technology to life	Declaration of Conformity		DoC-034 Revision Number: 110
	S1028: Intubation and Endotracheal Tubes		

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	Ila	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	Ila	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	Ila	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	Ila	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	Ila	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	Ila	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	Ila	5

 bringing technology to life	Declaration of Conformity	DoC-034
	S1028: Intubation and Endotracheal Tubes	Revision Number: 110

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	Ila	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	Ila	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	Ila	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	Ila	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	Ila	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	Ila	5

 bringing technology to life	Declaration of Conformity	
	S1028: Intubation and Endotracheal Tubes	DoC-034 Revision Number: 110

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	Ila	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	Ila	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	Ila	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	Ila	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	Ila	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	Ila	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	Ila	5

 bringing technology to life	Declaration of Conformity	DoC-034
	S1028: Intubation and Endotracheal Tubes	Revision Number: 110

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	Ila	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	Ila	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	Ila	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	Ila	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	Ila	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	Ila	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	Ila	5

 bringing technology to life	Declaration of Conformity		DoC-034 Revision Number: 110
	S1028: Intubation and Endotracheal Tubes		

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	Ila	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	Ila	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	Ila	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	Ila	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	Ila	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	Ila	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	Ila	5



Declaration of Conformity

S1028: Intubation and Endotracheal Tubes

DoC-034
Revision Number: 110

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	Ila	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	Ila	5

 bringing technology to life	Declaration of Conformity	
	S1028: Intubation and Endotracheal Tubes	DoC-034 Revision Number: 110

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. Product description and classification correction for L957 and L958. Removal of obsolete codes: 100/420/150 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 DV SOP2005: 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. 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

 bringing technology to life	Declaration of Conformity		DoC-034
	S1028: Intubation and Endotracheal Tubes		Revision Number: 110

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 Smlak.		
110	Updated to newest template revision (003 to 104). Updated STED title from "Intubation Systems Endotracheal Tubes" to "Intubation and Endotracheal Tubes" to reflect the STED's description in Agile. Changed the legal manufacturer from MHYT to MMSP as per FM-DVSOP8005-05 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. 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. Changed the EC Certificate from CE 661325 to CE 669121 due to the Legal Manufacturer change. Changed Product Scope from "Intubation Systems" to "Sterile and non-sterile Applications for patient Intubation" to align with EC Certificate 669121. Revised SKU descriptions to match description field in Agile. Deleted L957 and L958 from Appendix 1. Both L957 and L958 are Post-Phase Out. 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. 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