

	Declaration of Conformity	DoC-060 Revision Number: 110
	S1054: Portex Tracheostomy 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 - Mesto
753 01 Hranice, Czech Republic

Product Tradename(s): Blue Line® tracheostomy tube, Blue Line Ultra® tracheostomy tubes,
UniPerc® tracheostomy apparatus, Suctionaid® tracheostomy tubes,
Vocalaid™ tracheostomy tube and Orator™

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: 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: 23 Aug 2019

Name: Stacy Novak

Title: Sr. Manager, Regulatory Operations

Location of Signatory: Minneapolis, MN, US

	Declaration of Conformity	DoC-060 Revision Number: 110
	S1054: Portex Tracheostomy Tubes	

Appendix 1: Product List

Num	External Reference Number	Internal Reference Number	Product Description	Manufacturing Site	UMDNS (if applicable)	GMDN Code	EU Risk Class	EU Rule
1.	100/506/030	100/506/030	Tracheostomy 3.0MM Uncuffed 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	35404	IIb	8
2.	100/506/035	100/506/035	Tracheostomy 3.5MM Uncuffed 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	35404	IIb	8
3.	100/506/040	100/506/040	Tracheostomy 4.0MM Uncuffed 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	35404	IIb	8
4.	100/506/045	100/506/045	Tracheostomy 4.5MM Uncuffed 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	35404	IIb	8
5.	100/506/050	100/506/050	Tracheostomy 5.0MM Uncuffed 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	35404	IIb	8
6.	100/506/060	100/506/060	Tracheostomy 6.0MM Uncuffed 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	35404	IIb	8
7.	100/506/070	100/506/070	Tracheostomy 7.0MM Uncuffed 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	35404	IIb	8

	Declaration of Conformity	DoC-060 Revision Number: 110
	S1054: Portex Tracheostomy Tubes	

Num	External Reference Number	Internal Reference Number	Product Description	Manufacturing Site	UMDNS (if applicable)	GMDN Code	EU Risk Class	EU Rule
8.	100/506/075	100/506/075	Tracheostomy 7.5MM Uncuffed 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	35404	Ilb	8
9.	100/506/080	100/506/080	Tracheostomy 8.0MM Uncuffed 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	35404	Ilb	8
10.	100/506/090	100/506/090	Tracheostomy 9.0MM Uncuffed 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	35404	Ilb	8
11.	100/510/060	100/510/060	Tracheostomy 6.0MM Trad Cuff 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	35404	Ilb	8
12.	100/510/070	100/510/070	Tracheostomy 7.0MM Trad Cuff 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	35404	Ilb	8
13.	100/510/075	100/510/075	Tracheostomy 7.5MM Trad Cuff 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	35404	Ilb	8
14.	100/510/080	100/510/080	Tracheostomy 8.0MM Trad Cuff 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	35404	Ilb	8

	Declaration of Conformity	DoC-060 Revision Number: 110
	S1054: Portex Tracheostomy Tubes	

Num	External Reference Number	Internal Reference Number	Product Description	Manufacturing Site	UMDNS (if applicable)	GMDN Code	EU Risk Class	EU Rule
15.	100/510/090	100/510/090	Tracheostomy 9.0MM Trad Cuff 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	35404	Ilb	8
16.	100/510/100	100/510/100	Tracheostomy 10.0MM Trad Cuff 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	35404	Ilb	8
17.	100/512/070	100/512/070	Tracheostomy 7.0MM 15MM Conn 2xHigh Vol Low Pressure Cuff	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P 22425 Mexico	N/A	35404	Ilb	8
18.	100/512/075	100/512/075	Tracheostomy 7.5MM 15MM Conn 2xHigh Vol Low Pressure Cuff	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P 22425 Mexico	N/A	35404	Ilb	8
19.	100/512/080	100/512/080	Tracheostomy 8.0MM 15MM Conn 2xHigh Vol Low Pressure Cuff	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P 22425 Mexico	N/A	35404	Ilb	8
20.	100/512/090	100/512/090	Tracheostomy 9.0MM 15MM Conn 2xHigh Vol Low Pressure Cuff	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P 22425 Mexico	N/A	35404	Ilb	8
21.	100/512/100	100/512/100	Tracheostomy 10.0MM 15MM Conn 2xHigh Vol Low Pressure Cuff	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P 22425 Mexico	N/A	35404	Ilb	8

	Declaration of Conformity	DoC-060 Revision Number: 110
	S1054: Portex Tracheostomy Tubes	

Num	External Reference Number	Internal Reference Number	Product Description	Manufacturing Site	UMDNS (if applicable)	GMDN Code	EU Risk Class	EU Rule
22.	100/515/060	100/515/060	Suctionaid Tracheostomy 6.0MM Soft Seal Cuff	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P 22425 Mexico	N/A	35404	IIb	8
23.	100/515/070	100/515/070	Suctionaid Tracheostomy 7.0MM Soft Seal Cuff	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P 22425 Mexico	N/A	35404	IIb	8
24.	100/515/075	100/515/075	Suctionaid Tracheostomy 7.5MM Soft Seal Cuff	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P 22425 Mexico	N/A	35404	IIb	8
25.	100/515/080	100/515/080	Suctionaid Tracheostomy 8.0MM Soft Seal Cuff	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P 22425 Mexico	N/A	35404	IIb	8
26.	100/515/090	100/515/090	Suctionaid Tracheostomy 9.0MM Soft Seal Cuff	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P 22425 Mexico	N/A	35404	IIb	8
27.	100/515/100	100/515/100	Suctionaid Tracheostomy 10.0MM Soft Seal Cuff	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P 22425 Mexico	N/A	35404	IIb	8
28.	100/517/060	100/517/060	Tracheostomy Vocalaid 6.0MM 15MM Connector Profile Cuff	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P 22425 Mexico	N/A	35404	IIb	8

	Declaration of Conformity	DoC-060 Revision Number: 110
	S1054: Portex Tracheostomy Tubes	

Num	External Reference Number	Internal Reference Number	Product Description	Manufacturing Site	UMDNS (if applicable)	GMDN Code	EU Risk Class	EU Rule
29.	100/517/070	100/517/070	Tracheostomy Vocalaid 7.0MM 15MM Connector Profile Cuff	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P 22425 Mexico	N/A	35404	IIb	8
30.	100/517/075	100/517/075	Tracheostomy Vocalaid 7.5MM 15MM Connector Profile Cuff	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P 22425 Mexico	N/A	35404	IIb	8
31.	100/517/080	100/517/080	Tracheostomy Vocalaid 8.0MM 15MM Connector Profile Cuff	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P 22425 Mexico	N/A	35404	IIb	8
32.	100/517/090	100/517/090	Tracheostomy Vocalaid 9.0MM 15MM Connector Profile Cuff	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P 22425 Mexico	N/A	35404	IIb	8
33.	100/517/100	100/517/100	Tracheostomy Vocalaid 10.0MM 15MM Connector Profile Cuff	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P 22425 Mexico	N/A	35404	IIb	8
34.	100/518/060	100/518/060	Tracheostomy 6.0MM Prof Cuff 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	35404	IIb	8
35.	100/518/070	100/518/070	Tracheostomy 7.0MM Prof Cuff 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	35404	IIb	8

	Declaration of Conformity	DoC-060 Revision Number: 110
	S1054: Portex Tracheostomy Tubes	

Num	External Reference Number	Internal Reference Number	Product Description	Manufacturing Site	UMDNS (if applicable)	GMDN Code	EU Risk Class	EU Rule
36.	100/518/075	100/518/075	Tracheostomy 7.5MM Prof Cuff 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	35404	Ilb	8
37.	100/518/080	100/518/080	Tracheostomy 8.0MM Prof Cuff 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	35404	Ilb	8
38.	100/518/090	100/518/090	Tracheostomy 9.0MM Prof Cuff 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	35404	Ilb	8
39.	100/518/100	100/518/100	Tracheostomy 10.0MM Prof Cuff 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	35404	Ilb	8
40.	100/535/030	100/535/030	Tracheostomy 3.0MM Uncuffed 1xFenestration w/o 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	35404	Ilb	8
41.	100/535/035	100/535/035	Tracheostomy 3.5MM Uncuffed 1xFenestration w/o 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	35404	Ilb	8
42.	100/535/040	100/535/040	Tracheostomy 4.0MM Uncuffed 1xFenestration w/o 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	35404	Ilb	8

 bringing technology to life	Declaration of Conformity	DoC-060 Revision Number: 110
	S1054: Portex Tracheostomy Tubes	

Num	External Reference Number	Internal Reference Number	Product Description	Manufacturing Site	UMDNS (if applicable)	GMDN Code	EU Risk Class	EU Rule
43.	100/535/045	100/535/045	Tracheostomy 4.5MM Uncuffed 1xFenestration w/o 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	35404	IIb	8
44.	100/535/050	100/535/050	Tracheostomy 5.0MM Uncuffed 1xFenestration w/o 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	35404	IIb	8
45.	100/535/075	100/535/075	Tracheostomy 7.5MM Uncuffed 1xFenestration w/o 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	35404	IIb	8
46.	100/535/090	100/535/090	Tracheostomy 9.0MM Uncuffed 1xFenestration w/o 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	35404	IIb	8
47.	100/535/100	100/535/100	Tracheostomy 10.0MM Uncuffed 1xFenestration w/o 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	35404	IIb	8
48.	100/536/030	100/536/030	Tracheostomy 3.0MM Uncuffed 1xFenestration 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	35404	IIb	8
49.	100/536/035	100/536/035	Tracheostomy 3.5MM Uncuffed 1xFenestration 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	35404	IIb	8

	Declaration of Conformity	DoC-060 Revision Number: 110
	S1054: Portex Tracheostomy Tubes	

Num	External Reference Number	Internal Reference Number	Product Description	Manufacturing Site	UMDNS (if applicable)	GMDN Code	EU Risk Class	EU Rule
50.	100/536/040	100/536/040	Tracheostomy 4.0MM Uncuffed 1xFenestration 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	35404	IIb	8
51.	100/536/045	100/536/045	Tracheostomy 4.5MM Uncuffed 1xFenestration 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	35404	IIb	8
52.	100/536/050	100/536/050	Tracheostomy 5.0MM Uncuffed 1xFenestration 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	35404	IIb	8
53.	100/536/060	100/536/060	Tracheostomy 6.0MM Uncuffed 1xFenestration 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	35404	IIb	8
54.	100/536/070	100/536/070	Tracheostomy 7.0MM Uncuffed 1xFenestration 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	35404	IIb	8
55.	100/536/075	100/536/075	Tracheostomy 7.5MM Uncuffed 1xFenestration 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	35404	IIb	8
56.	100/536/080	100/536/080	Tracheostomy 8.0MM Uncuffed 1xFenestration 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	35404	IIb	8

 bringing technology to life	Declaration of Conformity	DoC-060 Revision Number: 110
	S1054: Portex Tracheostomy Tubes	

Num	External Reference Number	Internal Reference Number	Product Description	Manufacturing Site	UMDNS (if applicable)	GMDN Code	EU Risk Class	EU Rule
57.	100/536/090	100/536/090	Tracheostomy 9.0MM Uncuffed 1xFenestration 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	35404	Ilb	8
58.	100/536/100	100/536/100	Tracheostomy 10.0MM Uncuffed 1xFenestration 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	35404	Ilb	8
59.	100/537/060	100/537/060	Tracheostomy 6.0MM Uncuffed 2xFenestration 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	35404	Ilb	8
60.	100/537/070	100/537/070	Tracheostomy 7.0MM Uncuffed 2xFenestration 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	35404	Ilb	8
61.	100/537/075	100/537/075	Tracheostomy 7.5MM Uncuffed 2xFenestration 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	35404	Ilb	8
62.	100/537/080	100/537/080	Tracheostomy 8.0MM Uncuffed 2xFenestration 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	35404	Ilb	8
63.	100/537/090	100/537/090	Tracheostomy 9.0MM Uncuffed 2xFenestration 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	35404	Ilb	8

	Declaration of Conformity	DoC-060 Revision Number: 110
	S1054: Portex Tracheostomy Tubes	

Num	External Reference Number	Internal Reference Number	Product Description	Manufacturing Site	UMDNS (if applicable)	GMDN Code	EU Risk Class	EU Rule
64.	100/537/100	100/537/100	Tracheostomy 10.0MM Uncuffed 2xFenestration 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	35404	Ilb	8
65.	100/539/060	100/539/060	Blue Line Tracheostomy Tube, 15MM Connector, Profile Cuff, 2 x Fenestration – 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	35404	Ilb	8
66.	100/539/070	100/539/070	Blue Line Tracheostomy Tube, 15MM Connector, Profile Cuff, 2 x Fenestration – 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	35404	Ilb	8
67.	100/539/075	100/539/075	Blue Line Tracheostomy Tube, 15MM Connector, Profile Cuff, 2 x Fenestration – 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	35404	Ilb	8
68.	100/539/080	100/539/080	Blue Line Tracheostomy Tube, 15MM Connector, Profile Cuff, 2 x Fenestration – 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	35404	Ilb	8
69.	100/539/090	100/539/090	Blue Line Tracheostomy Tube, 15MM Connector, Profile Cuff, 2 x Fenestration – 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	35404	Ilb	8
70.	100/800/060	100/800/060	BLU Trachy 6.0MM S/Seal Cuff	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P 22425 Mexico	N/A	35404	Ilb	8

	Declaration of Conformity	DoC-060 Revision Number: 110
	S1054: Portex Tracheostomy Tubes	

Num	External Reference Number	Internal Reference Number	Product Description	Manufacturing Site	UMDNS (if applicable)	GMDN Code	EU Risk Class	EU Rule
71.	100/800/060	100/800/060CZ	BLU Trachy 6.0MM S/Seal Cuff	Smiths Medical Czech Republic a.s Olomoucka 306, 753 01 Hranice, Czech Republic	N/A	35404	Ilb	8
72.	100/800/070	100/800/070	BLU Trachy 7.0MM S/Seal Cuff	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P 22425 Mexico	N/A	35404	Ilb	8
73.	100/800/070	100/800/070CZ	BLU Trachy 7.0MM S/Seal Cuff	Smiths Medical Czech Republic a.s Olomoucka 306, 753 01 Hranice, Czech Republic	N/A	35404	Ilb	8
74.	100/800/075	100/800/075	BLU Trachy 7.5MM S/Seal Cuff	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P 22425 Mexico	N/A	35404	Ilb	8
75.	100/800/075	100/800/075CZ	BLU Trachy 7.5MM S/Seal Cuff	Smiths Medical Czech Republic a.s Olomoucka 306, 753 01 Hranice, Czech Republic	N/A	35404	Ilb	8
76.	100/800/080	100/800/080	BLU Trachy 8.0MM S/Seal Cuff	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P 22425 Mexico	N/A	35404	Ilb	8
77.	100/800/080	100/800/080CZ	BLU Trachy 8.0MM S/Seal Cuff	Smiths Medical Czech Republic a.s Olomoucka 306, 753 01 Hranice, Czech Republic	N/A	35404	Ilb	8
78.	100/800/085	100/800/085	BLU Trachy 8.5MM S/Seal Cuff	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P 22425 Mexico	N/A	35404	Ilb	8
79.	100/800/085	100/800/085CZ	BLU Trachy 8.5MM S/Seal Cuff	Smiths Medical Czech Republic a.s Olomoucka 306, 753 01 Hranice, Czech Republic	N/A	35404	Ilb	8

	Declaration of Conformity	DoC-060 Revision Number: 110
	S1054: Portex Tracheostomy Tubes	

Num	External Reference Number	Internal Reference Number	Product Description	Manufacturing Site	UMDNS (if applicable)	GMDN Code	EU Risk Class	EU Rule
80.	100/800/090	100/800/090	BLU Trachy 9.0MM S/Seal Cuff	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P 22425 Mexico	N/A	35404	IIb	8
81.	100/800/090	100/800/090CZ	BLU Trachy 9.0MM S/Seal Cuff	Smiths Medical Czech Republic a.s Olomoucka 306, 753 01 Hranice, Czech Republic	N/A	35404	IIb	8
82.	100/800/100	100/800/100	BLU Trachy 10.0MM S/Seal Cuff	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P 22425 Mexico	N/A	35404	IIb	8
83.	100/800/100	100/800/100CZ	BLU Trachy 10.0MM S/Seal Cuff	Smiths Medical Czech Republic a.s Olomoucka 306, 753 01 Hranice, Czech Republic	N/A	35404	IIb	8
84.	100/802/060	100/802/060	BLU Trachy, S/Seal, Fenes. 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	35404	IIb	8
85.	100/802/060	100/802/060CZ	BLU Trachy, S/Seal, Fenes. 6.0MM	Smiths Medical Czech Republic a.s Olomoucka 306, 753 01 Hranice, Czech Republic	N/A	35404	IIb	8
86.	100/802/070	100/802/070	BLU Trachy, S/Seal, Fenes. 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	35404	IIb	8
87.	100/802/070	100/802/070CZ	BLU Trachy, S/Seal, Fenes. 7.0MM	Smiths Medical Czech Republic a.s Olomoucka 306, 753 01 Hranice, Czech Republic	N/A	35404	IIb	8
88.	100/802/075	100/802/075	BLU Trachy, S/Seal, Fenes. 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	35404	IIb	8

	Declaration of Conformity	DoC-060 Revision Number: 110
	S1054: Portex Tracheostomy Tubes	

Num	External Reference Number	Internal Reference Number	Product Description	Manufacturing Site	UMDNS (if applicable)	GMDN Code	EU Risk Class	EU Rule
89.	100/802/075	100/802/075CZ	BLU Trachy, S/Seal, Fenes. 7.5MM	Smiths Medical Czech Republic a.s Olomoucka 306, 753 01 Hranice, Czech Republic	N/A	35404	Ilb	8
90.	100/802/080	100/802/080	BLU Trachy, S/Seal, Fenes. 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	35404	Ilb	8
91.	100/802/080	100/802/080CZ	BLU Trachy, S/Seal, Fenes. 8.0MM	Smiths Medical Czech Republic a.s Olomoucka 306, 753 01 Hranice, Czech Republic	N/A	35404	Ilb	8
92.	100/802/085	100/802/085	BLU Trachy, S/Seal, Fenes. 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	35404	Ilb	8
93.	100/802/085	100/802/085CZ	BLU Trachy, S/Seal, Fenes. 8.5MM	Smiths Medical Czech Republic a.s Olomoucka 306, 753 01 Hranice, Czech Republic	N/A	35404	Ilb	8
94.	100/802/090	100/802/090	BLU Trachy, S/Seal, Fenes. 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	35404	Ilb	8
95.	100/802/090	100/802/090CZ	BLU Trachy, S/Seal, Fenes. 9.0MM	Smiths Medical Czech Republic a.s Olomoucka 306, 753 01 Hranice, Czech Republic	N/A	35404	Ilb	8
96.	100/802/100	100/802/100	BLU Trachy, S/Seal, Fenes. 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	35404	Ilb	8
97.	100/802/100	100/802/100CZ	BLU Trachy, S/Seal, Fenes. 10.0MM	Smiths Medical Czech Republic a.s Olomoucka 306, 753 01 Hranice, Czech Republic	N/A	35404	Ilb	8

	Declaration of Conformity	DoC-060 Revision Number: 110
	S1054: Portex Tracheostomy Tubes	

Num	External Reference Number	Internal Reference Number	Product Description	Manufacturing Site	UMDNS (if applicable)	GMDN Code	EU Risk Class	EU Rule
98.	100/860/060	100/860/060	B/L Ultra Suctionaid 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	35404	IIb	8
99.	100/860/060	100/860/060CZ	B/L Ultra Suctionaid 6.0MM	Smiths Medical Czech Republic a.s Olomoucka 306, 753 01 Hranice, Czech Republic	N/A	35404	IIb	8
100.	100/860/070	100/860/070	B/L Ultra Suctionaid 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	35404	IIb	8
101.	100/860/070	100/860/070CZ	B/L Ultra Suctionaid 7.0MM	Smiths Medical Czech Republic a.s Olomoucka 306, 753 01 Hranice, Czech Republic	N/A	35404	IIb	8
102.	100/860/075	100/860/075	B/L Ultra Suctionaid 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	35404	IIb	8
103.	100/860/075	100/860/075CZ	B/L Ultra Suctionaid 7.5MM	Smiths Medical Czech Republic a.s Olomoucka 306, 753 01 Hranice, Czech Republic	N/A	35404	IIb	8
104.	100/860/080	100/860/080	B/L Ultra Suctionaid 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	35404	IIb	8
105.	100/860/080	100/860/080CZ	B/L Ultra Suctionaid 8.0MM	Smiths Medical Czech Republic a.s Olomoucka 306, 753 01 Hranice, Czech Republic	N/A	35404	IIb	8
106.	100/860/085	100/860/085	B/L Ultra Suctionaid 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	35404	IIb	8

	Declaration of Conformity	DoC-060 Revision Number: 110
	S1054: Portex Tracheostomy Tubes	

Num	External Reference Number	Internal Reference Number	Product Description	Manufacturing Site	UMDNS (if applicable)	GMDN Code	EU Risk Class	EU Rule
107.	100/860/085	100/860/085CZ	B/L Ultra Suctionaid 8.5MM	Smiths Medical Czech Republic a.s Olomoucka 306, 753 01 Hranice, Czech Republic	N/A	35404	Ilb	8
108.	100/860/090	100/860/090	B/L Ultra Suctionaid 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	35404	Ilb	8
109.	100/860/090	100/860/090CZ	B/L Ultra Suctionaid 9.0MM	Smiths Medical Czech Republic a.s Olomoucka 306, 753 01 Hranice, Czech Republic	N/A	35404	Ilb	8
110.	100/860/100	100/860/100	B/L Ultra Suctionaid 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	35404	Ilb	8
111.	100/860/100	100/860/100CZ	B/L Ultra Suctionaid 10.0MM	Smiths Medical Czech Republic a.s Olomoucka 306, 753 01 Hranice, Czech Republic	N/A	35404	Ilb	8
112.	100/810/060	100/810/060	B/L Ultra Tracheostomy 6.0MM S/Seal Cuff, Smooth Inner Cann	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P 22425 Mexico	N/A	35404	Ilb	8
113.	100/810/060	100/810/060CZ	B/L Ultra Tracheostomy 6.0MM S/Seal Cuff, Smooth Inner Cann	Smiths Medical Czech Republic a.s Olomoucka 306, 753 01 Hranice, Czech Republic	N/A	35404	Ilb	8
114.	100/810/070	100/810/070	B/L Ultra Tracheostomy 7.0MM S/Seal Cuff, Smooth Inner Cann	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P 22425 Mexico	N/A	35404	Ilb	8
115.	100/810/070	100/810/070CZ	B/L Ultra Tracheostomy 7.0MM S/Seal Cuff, Smooth Inner Cann	Smiths Medical Czech Republic a.s Olomoucka 306, 753 01 Hranice, Czech Republic	N/A	35404	Ilb	8

	Declaration of Conformity	DoC-060 Revision Number: 110
	S1054: Portex Tracheostomy Tubes	

Num	External Reference Number	Internal Reference Number	Product Description	Manufacturing Site	UMDNS (if applicable)	GMDN Code	EU Risk Class	EU Rule
116.	100/810/075	100/810/075	B/L Ultra Tracheostomy 7.5MM S/Seal Cuff, Smooth Inner Cann	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P 22425 Mexico	N/A	35404	IIb	8
117.	100/810/075	100/810/075CZ	B/L Ultra Tracheostomy 7.5MM S/Seal Cuff, Smooth Inner Cann	Smiths Medical Czech Republic a.s Olomoucka 306, 753 01 Hranice, Czech Republic	N/A	35404	IIb	8
118.	100/810/080	100/810/080	B/L Ultra Tracheostomy 8.0MM S/Seal Cuff, Smooth Inner Cann	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P 22425 Mexico	N/A	35404	IIb	8
119.	100/810/080	100/810/080CZ	B/L Ultra Tracheostomy 8.0MM S/Seal Cuff, Smooth Inner Cann	Smiths Medical Czech Republic a.s Olomoucka 306, 753 01 Hranice, Czech Republic	N/A	35404	IIb	8
120.	100/810/085	100/810/085	B/L Ultra Tracheostomy 8.5MM S/Seal Cuff, Smooth Inner Cann	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P 22425 Mexico	N/A	35404	IIb	8
121.	100/810/085	100/810/085CZ	B/L Ultra Tracheostomy 8.5MM S/Seal Cuff, Smooth Inner Cann	Smiths Medical Czech Republic a.s Olomoucka 306, 753 01 Hranice, Czech Republic	N/A	35404	IIb	8
122.	100/810/090	100/810/090	B/L Ultra Tracheostomy 9.0MM S/Seal Cuff, Smooth Inner Cann	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P 22425 Mexico	N/A	35404	IIb	8
123.	100/810/090	100/810/090CZ	B/L Ultra Tracheostomy 9.0MM S/Seal Cuff, Smooth Inner Cann	Smiths Medical Czech Republic a.s Olomoucka 306, 753 01 Hranice, Czech Republic	N/A	35404	IIb	8
124.	100/810/100	100/810/100	B/L Ultra Tracheostomy 10.0MM S/Seal Cuff, Smooth Inner Cann	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P 22425 Mexico	N/A	35404	IIb	8

	Declaration of Conformity	DoC-060 Revision Number: 110
	S1054: Portex Tracheostomy Tubes	

Num	External Reference Number	Internal Reference Number	Product Description	Manufacturing Site	UMDNS (if applicable)	GMDN Code	EU Risk Class	EU Rule
125.	100/810/100	100/810/100CZ	B/L Ultra Tracheostomy 10.0MM S/Seal Cuff, Smooth Inner Cann	Smiths Medical Czech Republic a.s Olomoucka 306, 753 01 Hranice, Czech Republic	N/A	35404	Ilb	8
126.	100/811/060	100/811/060	BLU Tracheostomy Kit, 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	35404	Ilb	8
127.	100/811/060	100/811/060CZ	BLU Tracheostomy Kit, Uncuffed, 6.0MM	Smiths Medical Czech Republic a.s Olomoucka 306, 753 01 Hranice, Czech Republic	N/A	35404	Ilb	8
128.	100/811/070	100/811/070	BLU Tracheostomy Kit, 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	35404	Ilb	8
129.	100/811/070	100/811/070CZ	BLU Tracheostomy Kit, Uncuffed, 7.0MM	Smiths Medical Czech Republic a.s Olomoucka 306, 753 01 Hranice, Czech Republic	N/A	35404	Ilb	8
130.	100/811/075	100/811/075	BLU Tracheostomy Kit, 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	35404	Ilb	8
131.	100/811/075	100/811/075CZ	BLU Tracheostomy Kit, Uncuffed, 7.5MM	Smiths Medical Czech Republic a.s Olomoucka 306, 753 01 Hranice, Czech Republic	N/A	35404	Ilb	8
132.	100/811/080	100/811/080	BLU Tracheostomy Kit, 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	35404	Ilb	8
133.	100/811/080	100/811/080CZ	BLU Tracheostomy Kit, Uncuffed, 8.0MM	Smiths Medical Czech Republic a.s Olomoucka 306, 753 01 Hranice, Czech Republic	N/A	35404	Ilb	8

	Declaration of Conformity	DoC-060 Revision Number: 110
	S1054: Portex Tracheostomy Tubes	

Num	External Reference Number	Internal Reference Number	Product Description	Manufacturing Site	UMDNS (if applicable)	GMDN Code	EU Risk Class	EU Rule
134.	100/811/085	100/811/085	BLU Tracheostomy Kit, 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	35404	IIb	8
135.	100/811/085	100/811/085CZ	BLU Tracheostomy Kit, Uncuffed, 8.5MM	Smiths Medical Czech Republic a.s Olomoucka 306, 753 01 Hranice, Czech Republic	N/A	35404	IIb	8
136.	100/811/090	100/811/090	BLU Tracheostomy Kit, 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	35404	IIb	8
137.	100/811/090	100/811/090CZ	BLU Tracheostomy Kit, Uncuffed, 9.0MM	Smiths Medical Czech Republic a.s Olomoucka 306, 753 01 Hranice, Czech Republic	N/A	35404	IIb	8
138.	100/811/100	100/811/100	BLU Tracheostomy Kit, Uncuffed, 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	35404	IIb	8
139.	100/811/100	100/811/100CZ	BLU Tracheostomy Kit, Uncuffed, 10.0MM	Smiths Medical Czech Republic a.s Olomoucka 306, 753 01 Hranice, Czech Republic	N/A	35404	IIb	8
140.	100/812/060	100/812/060	B/L Ultra Tracheostomy 6.0MM S/Seal Cuff, Fenes., Inner Cann	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P 22425 Mexico	N/A	35404	IIb	8
141.	100/812/060	100/812/060CZ	B/L Ultra Tracheostomy 6.0MM S/Seal Cuff, Fenes., Inner Cann	Smiths Medical Czech Republic a.s Olomoucka 306, 753 01 Hranice, Czech Republic	N/A	35404	IIb	8
142.	100/812/070	100/812/070	B/L Ultra Tracheostomy 7.0MM S/Seal Cuff, Fenes., Inner Cann	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P 22425 Mexico	N/A	35404	IIb	8

	Declaration of Conformity	DoC-060 Revision Number: 110
	S1054: Portex Tracheostomy Tubes	

Num	External Reference Number	Internal Reference Number	Product Description	Manufacturing Site	UMDNS (if applicable)	GMDN Code	EU Risk Class	EU Rule
143.	100/812/070	100/812/070CZ	B/L Ultra Tracheostomy 7.0MM S/Seal Cuff, Fenes., Inner Cann	Smiths Medical Czech Republic a.s Olomoucka 306, 753 01 Hranice, Czech Republic	N/A	35404	Ilb	8
144.	100/812/075	100/812/075	B/L Ultra Tracheostomy 7.5MM S/Seal Cuff, Fenes., Inner Cann	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P 22425 Mexico	N/A	35404	Ilb	8
145.	100/812/075	100/812/075CZ	B/L Ultra Tracheostomy 7.5MM S/Seal Cuff, Fenes., Inner Cann	Smiths Medical Czech Republic a.s Olomoucka 306, 753 01 Hranice, Czech Republic	N/A	35404	Ilb	8
146.	100/812/080	100/812/080	B/L Ultra Tracheostomy 8.0MM S/Seal Cuff, Fenes., Inner Cann	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P 22425 Mexico	N/A	35404	Ilb	8
147.	100/812/080	100/812/080CZ	B/L Ultra Tracheostomy 8.0MM S/Seal Cuff, Fenes., Inner Cann	Smiths Medical Czech Republic a.s Olomoucka 306, 753 01 Hranice, Czech Republic	N/A	35404	Ilb	8
148.	100/812/085	100/812/085	B/L Ultra Tracheostomy 8.5MM S/Seal Cuff, Fenes., Inner Cann	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P 22425 Mexico	N/A	35404	Ilb	8
149.	100/812/085	100/812/085CZ	B/L Ultra Tracheostomy 8.5MM S/Seal Cuff, Fenes., Inner Cann	Smiths Medical Czech Republic a.s Olomoucka 306, 753 01 Hranice, Czech Republic	N/A	35404	Ilb	8
150.	100/812/090	100/812/090	B/L Ultra Tracheostomy 9.0MM S/Seal Cuff, Fenes., Inner Cann	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P 22425 Mexico	N/A	35404	Ilb	8
151.	100/812/090	100/812/090CZ	B/L Ultra Tracheostomy 9.0MM S/Seal Cuff, Fenes., Inner Cann	Smiths Medical Czech Republic a.s Olomoucka 306, 753 01 Hranice, Czech Republic	N/A	35404	Ilb	8

	Declaration of Conformity	DoC-060 Revision Number: 110
	S1054: Portex Tracheostomy Tubes	

Num	External Reference Number	Internal Reference Number	Product Description	Manufacturing Site	UMDNS (if applicable)	GMDN Code	EU Risk Class	EU Rule
152.	100/812/100	100/812/100	B/L Ultra Tracheostomy 10.0MM S/Seal Cuff, Fenes., Inner Cann	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P 22425 Mexico	N/A	35404	IIb	8
153.	100/812/100	100/812/100CZ	B/L Ultra Tracheostomy 10.0MM S/Seal Cuff, Fenes., Inner Cann	Smiths Medical Czech Republic a.s Olomoucka 306, 753 01 Hranice, Czech Republic	N/A	35404	IIb	8
154.	100/813/060	100/813/060	B/L Ultra Tracheostomy 6.0MM Uncuffed, Fenes., Inner Cannula	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P 22425 Mexico	N/A	35404	IIb	8
155.	100/813/060	100/813/060CZ	B/L Ultra Tracheostomy 6.0MM Uncuffed, Fenes., Inner Cannula	Smiths Medical Czech Republic a.s Olomoucka 306, 753 01 Hranice, Czech Republic	N/A	35404	IIb	8
156.	100/813/070	100/813/070	B/L Ultra Tracheostomy 7.0MM Uncuffed, Fenes., Inner Cannula	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P 22425 Mexico	N/A	35404	IIb	8
157.	100/813/070	100/813/070CZ	B/L Ultra Tracheostomy 7.0MM Uncuffed, Fenes., Inner Cannula	Smiths Medical Czech Republic a.s Olomoucka 306, 753 01 Hranice, Czech Republic	N/A	35404	IIb	8
158.	100/813/075	100/813/075	B/L Ultra Tracheostomy 7.5MM Uncuffed, Fenes., Inner Cannula	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P 2242, Mexico	N/A	35404	IIb	8
159.	100/813/075	100/813/075CZ	B/L Ultra Tracheostomy 7.5MM Uncuffed, Fenes., Inner Cannula	Smiths Medical Czech Republic a.s Olomoucka 306, 753 01 Hranice, Czech Republic	N/A	35404	IIb	8
160.	100/813/080	100/813/080	B/L Ultra Tracheostomy 8.0MM Uncuffed, Fenes., Inner Cannula	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P 22425 Mexico	N/A	35404	IIb	8

	Declaration of Conformity	DoC-060 Revision Number: 110
	S1054: Portex Tracheostomy Tubes	

Num	External Reference Number	Internal Reference Number	Product Description	Manufacturing Site	UMDNS (if applicable)	GMDN Code	EU Risk Class	EU Rule
161.	100/813/080	100/813/080CZ	B/L Ultra Tracheostomy 8.0MM Uncuffed, Fenes., Inner Cannula	Smiths Medical Czech Republic a.s Olomoucka 306, 753 01 Hranice, Czech Republic	N/A	35404	Ilb	8
162.	100/813/085	100/813/085	B/L Ultra Tracheostomy 8.5MM Uncuffed, Fenes., Inner Cannula	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P 22425 Mexico	N/A	35404	Ilb	8
163.	100/813/085	100/813/085CZ	B/L Ultra Tracheostomy 8.5MM Uncuffed, Fenes., Inner Cannula	Smiths Medical Czech Republic a.s Olomoucka 306, 753 01 Hranice, Czech Republic	N/A	35404	Ilb	8
164.	100/813/090	100/813/090	B/L Ultra Tracheostomy 9.0MM Uncuffed, Fenes., Inner Cannula	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P 22425 Mexico	N/A	35404	Ilb	8
165.	100/813/090	100/813/090CZ	B/L Ultra Tracheostomy 9.0MM Uncuffed, Fenes., Inner Cannula	Smiths Medical Czech Republic a.s Olomoucka 306, 753 01 Hranice, Czech Republic	N/A	35404	Ilb	8
166.	100/813/100	100/813/100	B/L Ultra Tracheostomy 10.0MM Uncuffed, Fenes., Inner Cannula	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P 22425 Mexico	N/A	35404	Ilb	8
167.	100/813/100	100/813/100CZ	B/L Ultra Tracheostomy 10.0MM Uncuffed, Fenes., Inner Cannula	Smiths Medical Czech Republic a.s Olomoucka 306, 753 01 Hranice, Czech Republic	N/A	35404	Ilb	8
168.	100/815/060	100/815/060	Trach BLU Cuf 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	35404	Ilb	8
169.	100/815/070	100/815/070	Trach BLU Cuf 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	35404	Ilb	8

	Declaration of Conformity	DoC-060 Revision Number: 110
	S1054: Portex Tracheostomy Tubes	

Num	External Reference Number	Internal Reference Number	Product Description	Manufacturing Site	UMDNS (if applicable)	GMDN Code	EU Risk Class	EU Rule
170.	100/815/075	100/815/075	Trach BLU Cuf 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	35404	IIb	8
171.	100/815/080	100/815/080	Trach BLU Cuf 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	35404	IIb	8
172.	100/815/085	100/815/085	Trach BLU Cuf 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	35404	IIb	8
173.	100/815/090	100/815/090	Trach BLU Cuf 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	35404	IIb	8
174.	100/815/100	100/815/100	Trach BLU 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	35404	IIb	8
175.	100/816/060	100/816/060	Trach BLU Uncf 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	35404	IIb	8
176.	100/816/070	100/816/070	Trach BLU Uncf 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	35404	IIb	8

	Declaration of Conformity	DoC-060 Revision Number: 110
	S1054: Portex Tracheostomy Tubes	

Num	External Reference Number	Internal Reference Number	Product Description	Manufacturing Site	UMDNS (if applicable)	GMDN Code	EU Risk Class	EU Rule
177.	100/816/075	100/816/075	Trach BLU Uncf 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	35404	IIb	8
178.	100/816/080	100/816/080	Trach BLU Uncf 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	35404	IIb	8
179.	100/816/085	100/816/085	Trach BLU Uncf 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	35404	IIb	8
180.	100/816/090	100/816/090	Trach BLU Uncf 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	35404	IIb	8
181.	100/816/100	100/816/100	Trach BLU Uncf 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	35404	IIb	8
182.	100/817/060	100/817/060	Trach BLU Cuf Fen 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	35404	IIb	8
183.	100/817/070	100/817/070	Trach BLU Cuf Fen 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	35404	IIb	8

	Declaration of Conformity	DoC-060 Revision Number: 110
	S1054: Portex Tracheostomy Tubes	

Num	External Reference Number	Internal Reference Number	Product Description	Manufacturing Site	UMDNS (if applicable)	GMDN Code	EU Risk Class	EU Rule
184.	100/817/080	100/817/080	Trach BLU Cuf Fen 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	35404	IIb	8
185.	100/817/090	100/817/090	Trach BLU Cuf Fen 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	35404	IIb	8
186.	100/817/100	100/817/100	Trach BLU Cuf Fen 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	35404	IIb	8
187.	100/818/060	100/818/060	Trach BLU Uncf Fen 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	35404	IIb	8
188.	100/818/070	100/818/070	Trach BLU Uncf Fen 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	35404	IIb	8
189.	100/818/080	100/818/080	Trach BLU Uncf Fen 8.00MM	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P 22425 Mexico	N/A	35404	IIb	8
190.	100/818/090	100/818/090	Trach BLU Uncf Fen 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	35404	IIb	8

	Declaration of Conformity	DoC-060 Revision Number: 110
	S1054: Portex Tracheostomy Tubes	

Num	External Reference Number	Internal Reference Number	Product Description	Manufacturing Site	UMDNS (if applicable)	GMDN Code	EU Risk Class	EU Rule
191.	100/818/100	100/818/100	Trach BLU Uncf Fen 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	35404	IIb	8
192.	100/832/070	100/832/070	BLU Tracheostomy Kit, Fenes., S/S 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	14099	IIb	8
193.	100/832/080	100/832/080	BLU Tracheostomy Kit, Fenes., S/S 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	14099	IIb	8
194.	100/832/090	100/832/090	BLU Tracheostomy Kit, Fenes., S/S 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	14099	IIb	8
195.	100/833/070	100/833/070	BLU Trachy Kit, Plain, Fenes, I/Cann, Speak Valve 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	14099	IIb	8
196.	100/833/070	100/833/070CZ	BLU Trachy Kit, Plain, Fenes, I/Cann, Speak Valve 7.0MM	Smiths Medical Czech Republic a.s Olomoucka 306, 753 01 Hranice, Czech Republic	N/A	14099	IIb	8
197.	100/870/060	100/870/060	B/L Ultra Suctionaid Kit Trachy Kit, S/S Cuff, Inner Cann 6MM	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P 22425 Mexico	N/A	35404	IIb	8
198.	100/870/060	100/870/060CZ	B/L Ultra Suctionaid Kit Trachy Kit, S/S Cuff, Inner Cann 6MM	Smiths Medical Czech Republic a.s Olomoucka 306, 753 01 Hranice, Czech Republic	N/A	35404	IIb	8

	Declaration of Conformity	DoC-060 Revision Number: 110
	S1054: Portex Tracheostomy Tubes	

Num	External Reference Number	Internal Reference Number	Product Description	Manufacturing Site	UMDNS (if applicable)	GMDN Code	EU Risk Class	EU Rule
199.	100/870/070	100/870/070	B/L Ultra Suctionaid W/Inn Can 7MM	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P 22425 Mexico	N/A	35404	IIb	8
200.	100/870/070	100/870/070CZ	B/L Ultra Suctionaid W/Inn Can 7MM	Smiths Medical Czech Republic a.s Olomoucka 306, 753 01 Hranice, Czech Republic	N/A	35404	IIb	8
201.	100/870/075	100/870/075	B/L Ultra Suctionaid Kit 7.5MM Trachy Kit, S/S Cuff, Inner Cann 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	35404	IIb	8
202.	100/870/075	100/870/075CZ	B/L Ultra Suctionaid Kit 7.5MM Trachy Kit, S/S Cuff, Inner Cann 7.5MM	Smiths Medical Czech Republic a.s Olomoucka 306, 753 01 Hranice, Czech Republic	N/A	35404	IIb	8
203.	100/870/080	100/870/080	B/L Ultra Suctionaid W/Inn Cann 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	35404	IIb	8
204.	100/870/080	100/870/080CZ	B/L Ultra Suctionaid W/Inn Cann 8.0MM	Smiths Medical Czech Republic a.s Olomoucka 306, 753 01 Hranice, Czech Republic	N/A	35404	IIb	8
205.	100/870/085	100/870/085	B/L Ultra Suctionaid W/Inn Cann 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	35404	IIb	8
206.	100/870/085	100/870/085CZ	B/L Ultra Suctionaid W/Inn Cann 8.5MM	Smiths Medical Czech Republic a.s Olomoucka 306, 753 01 Hranice, Czech Republic	N/A	35404	IIb	8
207.	100/870/090	100/870/090	B/L Ultra Suctionaid W/Inn Cann 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	35404	IIb	8

	Declaration of Conformity	DoC-060 Revision Number: 110
	S1054: Portex Tracheostomy Tubes	

Num	External Reference Number	Internal Reference Number	Product Description	Manufacturing Site	UMDNS (if applicable)	GMDN Code	EU Risk Class	EU Rule
208.	100/870/090	100/870/090CZ	B/L Ultra Suctionaid W/Inn Cann 9.0MM	Smiths Medical Czech Republic a.s Olomoucka 306, 753 01 Hranice, Czech Republic	N/A	35404	Ilb	8
209.	100/870/100	100/870/100	B/L Ultra Suctionaid W/Inn Cann 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	35404	Ilb	8
210.	100/870/100	100/870/100CZ	B/L Ultra Suctionaid W/Inn Cann 10.0MM	Smiths Medical Czech Republic a.s Olomoucka 306, 753 01 Hranice, Czech Republic	N/A	35404	Ilb	8
211.	100/875/060	100/875/060	Trach BLUS Cuf 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	35404	Ilb	8
212.	100/875/070	100/875/070	Trach BLUS Cuf 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	35404	Ilb	8
213.	100/875/075	100/875/075	Trach BLUS Cuf 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	35404	Ilb	8
214.	100/875/080	100/875/080	Trach BLUS Cuf 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	35404	Ilb	8
215.	100/875/085	100/875/085	Trach BLUS Cuf 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	35404	Ilb	8

	Declaration of Conformity	DoC-060 Revision Number: 110
	S1054: Portex Tracheostomy Tubes	

Num	External Reference Number	Internal Reference Number	Product Description	Manufacturing Site	UMDNS (if applicable)	GMDN Code	EU Risk Class	EU Rule
216.	100/875/090	100/875/090	Trach BLUS Cuf 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	35404	IIb	8
217.	100/875/100	100/875/100	Trach BLUS 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	35404	IIb	8
218.	100/523/060	100/523/060	Tracheostomy 6.0MM Adj Flange Siliconised Prof Cuff 15mmConn	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P 22425 Mexico	N/A	35404	IIb	5
219.	100/523/070	100/523/070	Tracheostomy 7.0MM Adj Flange Siliconised Prof Cuff 15mmConn	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P 22425 Mexico	N/A	35404	IIb	5
220.	100/523/080	100/523/080	Tracheostomy 8.0MM Adj Flange Siliconised Prof Cuff 15mmConn	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P 22425 Mexico	N/A	35404	IIb	5
221.	100/523/090	100/523/090	Tracheostomy 9.0MM Adj Flange Siliconised Prof Cuff 15mmConn	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P 22425 Mexico	N/A	35404	IIb	5
222.	100/523/100	100/523/100	Tracheostomy 10.0MM Adj Flange Siliconised Prof Cuff 15mmConn	Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P 22425 Mexico	N/A	35404	IIb	5

	Declaration of Conformity	DoC-060 Revision Number: 110
	S1054: Portex Tracheostomy Tubes	

Num	External Reference Number	Internal Reference Number	Product Description	Manufacturing Site	UMDNS (if applicable)	GMDN Code	EU Risk Class	EU Rule
223.	100/526/060	100/526/060	Tracheostomy 6.0MM Adj Flange Uncuffed Siliconised 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	35404	IIb	5
224.	100/526/070	100/526/070	Tracheostomy 7.0MM Adj Flange Uncuffed Siliconised 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	35404	IIb	5
225.	100/526/080	100/526/080	Tracheostomy 8.0MM Adj Flange Uncuffed Siliconised 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	35404	IIb	5
226.	100/526/090	100/526/090	Tracheostomy 9.0MM Adj Flange Uncuffed Siliconised 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	35404	IIb	5
227.	100/526/100	100/526/100	Tracheostomy 10.0MM Adj Flange Uncuffed Siliconised 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	35404	IIb	5
228.	100/897/070	100/897/070CZ	UniPerc Adjustable Flange Tracheostomy Tube Cuffed, 7mm	Smiths Medical Czech Republic a.s Olomoucka 306, 753 01 Hranice, Czech Republic	N/A	47657	IIb	8
229.	100/897/080	100/897/080CZ	UniPerc Adjustable Flange Tracheostomy Tube Cuffed, 8mm	Smiths Medical Czech Republic a.s Olomoucka 306, 753 01 Hranice, Czech Republic	N/A	47657	IIb	8
230.	100/897/090	100/897/090CZ	UniPerc Adjustable Flange Tracheostomy Tube Cuffed, 9mm	Smiths Medical Czech Republic a.s Olomoucka 306, 753 01 Hranice, Czech Republic	N/A	47657	IIb	8
231.	100/899/070	100/899/070CZ	UniPerc Adjustable Flange Tracheostomy Tube Uncuffed, 7mm	Smiths Medical Czech Republic a.s Olomoucka 306, 753 01 Hranice, Czech Republic	N/A	47657	IIb	8

	Declaration of Conformity	DoC-060 Revision Number: 110
	S1054: Portex Tracheostomy Tubes	

Num	External Reference Number	Internal Reference Number	Product Description	Manufacturing Site	UMDNS (if applicable)	GMDN Code	EU Risk Class	EU Rule
232.	100/899/080	100/899/080CZ	UniPerc Adjustable Flange Tracheostomy Tube Uncuffed, 8mm	Smiths Medical Czech Republic a.s Olomoucka 306, 753 01 Hranice, Czech Republic	N/A	47657	IIb	8
233.	100/899/090	100/899/090CZ	UniPerc Adjustable Flange Tracheostomy Tube Uncuffed, 9mm	Smiths Medical Czech Republic a.s Olomoucka 306, 753 01 Hranice, Czech Republic	N/A	47657	IIb	8
234.	100/550/000	100/550/000	Portex 'Orator' Speaking Valve for Tracheostomy Tube	Smiths Healthcare Manufacturing SA de CV Carretera Miguel Aleman Km 21.7, Parque Industrial Monterrey, Apodaca NL CP 66603 Mexico	N/A	36071	IIa	5

	Declaration of Conformity	DoC-060 Revision Number: 110
	S1054: Portex Tracheostomy Tubes	

Appendix 2: Revision History

Revision Number	Summary of Changes / Additions	Created / Revised by	Date (DD-MMM-YYYY Format)
05	Updated to new template, updated EC cert information	Lisa Hahne	13-DEC-2016
006	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 S1054 to DoC-060 and revision from 05 to 006 and added STED # to header for traceability to STED.	Stacy Novak	31-MAY-2017
007	The purpose of this revision update was in response to Notified Body Transfer. The Changes to this DoC include: Notified Body name from Intertek to BSI, added the product name in the header, updated to new certificate number from 053 01 A CE to CE 661325, changed the effective date, updated to new revision from 006 to 007 and removed the inactive SKU's from the DOC as follows: 100/509/060, 100/781/060, 100/781/070, 100/781/080, 100/781/090, 100/781/100, 100/782/060, 100/782/070, 100/782/080, 100/782/090, 100/782/100, 100/783/070, 100/783/090, 100/784/070, 100/784/080, 100/784/0990, 100/784/100, 100/785/070, 100/785/080, 100/785/090, 100/818/085, 100/825/060, 100/825/070, 100/825/075, 100/825/080, 100/825/085, 100/825/090, 100/825/100, 100/826/060, 100/826/070, 100/826/075, 100/826/080, 100/826/085, 100/826/090, 100/826/100, 100/885/060, 100/885/070, 100/885/075 100/885/080, 100/885/085, 100/897/090, 100/899/070, 100/899/080, 100/899/090, 100/527/060, 100/527/070, 100/527/080, 100/527/090, 100/527/100, 100/529/060, 100/529/070, 100/529/080, 100/529/090, and 100/529/100.	Manasa Boppana	22-AUG-2017
008	Updated DoC to the latest Template in Agile. Changed the Authorized Signatory from James Taufen to Stacy Novak. Removed the codes 100/897/070 and 100/897/080 because they were inadvertently missed from the group of product codes that were removed in Revision 007.	Mitchell Madsen	01-DEC-2017

	Declaration of Conformity	DoC-060 Revision Number: 110
	S1054: Portex Tracheostomy Tubes	

Revision Number	Summary of Changes / Additions	Created / Revised by	Date (DD-MMM-YYYY Format)
109	Updated to newest template revision (from 003 to 104). Changed the legal manufacturer from MHYT to MMSP as per FM-DVSOP8005-05. Added "Suctionaid® tracheostomy tubes, and Vocalaid™ tracheostomy tube" to product tradename(s) to capture all products listed. 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 661325 to 669121 due to the Legal Manufacturer change. Changed Product Scope from "Tracheostomy Tubes" to "Sterile and Non-Sterile tracheostomy accessories, Sterile Tracheostomy Tubes and Kits" to align with scoping expressions on EC Certificate 669121. Revised product descriptions to match the descriptions in Agile. Changed the GMDN Code for 100/810/070, 100/810/075, 100/810/080, 100/810/085, 100/810/090, 100/810/100, 100/811/060, 100/811/070, 100/811/075, 00/811/080, 100/811/085, 100/811/090, 100/811/100, 100/812/060, 100/812/070, 100/812/075, 100/812/080, 100/812/085, 100/812/090, 100/812/100, 100/813/060, 100/813/070, 100/813/075, 100/813/080, 100/813/085, 100/813/090, 100/813/100, 100/815/060 from 14099 to 35404 as the affected products are not considered kits. 35404 more accurately reflects the SKUs – confirmed by Nancy DeAngelo. Removed SKUs 100/509/070, 100/509/080, 100/509/090 and 100/509/100 as they are post-phase out and blocked in the EU.	Alicia Wilson	24-JUL-2019

	Declaration of Conformity	DoC-060 Revision Number: 110
	S1054: Portex Tracheostomy Tubes	

Revision Number	Summary of Changes / Additions	Created / Revised by	Date (DD-MMM-YYYY Format)
110	Add "Orator™" as a tradename due to the addition of SKU 100/550/000. Changed Product Scope from "Sterile and Non-Sterile tracheostomy accessories, Sterile Tracheostomy Tubes and Kits" to "Sterile Tracheostomy Tubes and Kits" as only the latter applies to this DoC. Split the "Catalog Number" column into two columns -- "External Reference Number" and "Internal Reference Number" to account for CZ codes. Added CZ codes from DoC-071 (includes 100/800/XXXCZ, 100/802/XXXCZ, 100/860/XXXCZ, 100/810/XXXCZ, 100/811/XXXCZ, 100/812/XXXCZ, 100/813/XXXCZ, 100/833/070CZ, and 100/870/XXXCZ) as the CZ and non-CZ SKUs are the same aside from the Manufacturing Site. Thus, the SKUs should be covered by the same DoC. Added 100/897/XXX and 100/899/XXX SKUs back onto the DoC as they are Inactive/Phase out, which indicates that they can still be commercially distributed. Also, 100/897/XXX and 100/899/XXX are the external reference numbers for the applicable CZ codes, which are still in Production/Saleable. As such, the CZ codes for 100/897/XXX and 100/899/XXX SKUs were moved to DoC-060 from DoC-071. Both CZ and non-CZ Codes were/are manufactured in Hranice. Added 100/550/000 from DoC-173 as DoC-173 is being obsoleted. 100/550/000 best aligns with the SKUs listed on DoC-060 per Nancy DeAngelo. Added EU Rule as "5" for 100/523/070 since it was unintentionally left blank in during the template update is revision 109. Changed the GMDN Code for 100/832/070 from 35404 to 14099. 100/832/070 is a kit, so 14099 is a better code fit. Changed the GMDN Code for 100/870/060 from 14099 to 35404. 100/870/060 is a tracheostomy tube, so 35404 is a better code fit.	Alicia Wilson	22-AUG-2019