smiths medical bringing technology to life	**Declaration of Conformity** S1029: Disposable Endotracheal Tube	DoC-035 Revision Number: 105

Legal Manufacturer:	Smiths Medical ASD, Inc. 6000 Nathan Lane North Minneapolis, MN 55442 USA
EU Representative:	Smiths Medical Czech Republic a. s. Olomoucká 306, Hranice 1 - Město, 753 01 Hranice, Czech Republic
Product Tradename(s):	Portex®
Conformity Assessment Route:	Annex V
Notified Body:	TUV SUD Product Service GmbH Zertifizierstellen Ridlerstraße 65 80339 MÜNCHEN Germany Notified Body #0123
EC Certificate Number:	G2 17 04 97063 002

Smiths Medical ASD, Inc. hereby declares under its sole responsibility that the product(s) referenced conform to the relevant provisions of the European Union Council Directive 93/42/EEC on Medical Devices (the MDD) as amended by Directive 2007/47/EC.

Authorized Signatory:

Signature: Stacy Novak Date: 28OCT2019

Name: Stacy Novak

Title: Director, Regulatory Operations

Location of Signatory: Minneapolis, MN, US

Appendix 1: Product List

Num	Catalog Number	Product Description	Manufacturing Site	GMDN Code	EU Risk Class	EU Rule
1.	100/150/050	5mm Portex Tracheal Tube	Jiangsu IAWA Bioscience Engineering Co., Ltd, 211Ji-An Rd,High-Tech Industrial Development Zone, Yangzhou, Jiangsu, China	46967	IIa	5
2.	100/150/055	5.5mm Portex Tracheal Tube	Jiangsu IAWA Bioscience Engineering Co., Ltd, 211Ji-An Rd, High-Tech Industrial Development Zone, Yangzhou, Jiangsu, China	46967	IIa	5
3.	100/150/060	6mm Portex Tracheal Tube	Jiangsu IAWA Bioscience Engineering Co., Ltd, 211Ji-An Rd, High-Tech Industrial Development Zone, Yangzhou, Jiangsu, China	46967	IIa	5
4.	100/150/065	6.5mm Portex Tracheal Tube	Jiangsu IAWA Bioscience Engineering Co., Ltd, 211Ji-An Rd, High-Tech Industrial Development Zone, Yangzhou, Jiangsu, China	46967	IIa	5
5.	100/150/070	7mm Portex Tracheal Tube	Jiangsu IAWA Bioscience Engineering Co., Ltd, 211Ji-An Rd, High-Tech Industrial Development Zone, Yangzhou, Jiangsu, China	46967	IIa	5
6.	100/150/075	7.5mm Portex Tracheal Tube	Jiangsu IAWA Bioscience Engineering Co., Ltd, 211Ji-An Rd, High-Tech Industrial Development Zone, Yangzhou, Jiangsu, China	46967	IIa	5
7.	100/150/080	8mm Portex Tracheal Tube	Jiangsu IAWA Bioscience Engineering Co., Ltd, 211Ji-An Rd, High-Tech Industrial Development Zone, Yangzhou, Jiangsu, China	46967	IIa	5

Num	Catalog Number	Product Description	Manufacturing Site	GMDN Code	EU Risk Class	EU Rule
8.	100/150/085	8.5mm Portex Tracheal Tube	Jiangsu IAWA Bioscience Engineering Co., Ltd, 211Ji-An Rd, High-Tech Industrial Development Zone, Yangzhou, Jiangsu, China	46967	IIa	5
9.	100/150/090	9mm Portex Tracheal Tube	Jiangsu IAWA Bioscience Engineering Co., Ltd, 211Ji-An Rd, High-Tech Industrial Development Zone, Yangzhou, Jiangsu, China	46967	IIa	5
10.	100/150/095	9.5mm Portex Tracheal Tube	Jiangsu IAWA Bioscience Engineering Co., Ltd, 211Ji-An Rd, High-Tech Industrial Development Zone, Yangzhou, Jiangsu, China	46967	IIa	5

Appendix 2: Revision History

Revision Number	Summary of Changes / Additions	Created / Revised by	Date
001	Transferring information from TF 07-05/02 to Global STED S1029, DoC number changing in accordance with new numbering system.	Kay Friend	01-OCT-2015
002	Changed manufacturer from Hythe to Minneapolis, MN; change Notified Body from Intertek to TUV	Stacy Novak	02-MAY-2017
003	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 S1029 to DoC-035 and revision from 002 to 003 and added STED # to header for traceability to STED.	Stacy Novak	31-MAY-2017
004	Updated DoC to the latest Template in Agile. Updated the CE Certificate Number from G1 17 04 97063 002 to G2 17 04 97063 002 to cover the above SKUs with the correct certificate. Changed Authorized Signatory from James Taufen to Stacy Novak.	Mitchell Madsen	08-DEC-2017
105	Changed the EU Representative from the Ashford, UK facility to the Hranice, Czech Republic facility. An EU Representative is needed if a product is commercially distributed in the EU and not manufactured in the EU. Since Ashford will no longer be part of the EU, due to Brexit, the EU Representative was changed from the Ashford facility to the Hranice facility. Updated to latest template revision (from 003 to 105). Added “Portex®” to reflect the tradename of the affected SKUs. Changed product descriptions to match the descriptions in Agile. Changed the STED title from “Breathing Systems – Endotracheal Tubes” to “Disposable Endotracheal Tube” to match the description in Agile. Revised the Manufacturing Site address for Jiangsu IAWA Bioscience Engineering Co., Ltd, to match the address listed in S1029.	Madi Johnson	24-OCT-2019