smiths medical bringing technology to life	**Declaration of Conformity** S1231: Blue Line Ultra (BLU) Tracheostomy Tubes	DoC-164 Revision Number: 102

Legal 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):	Portex®, Blue Line Ultra®, BLUselect®, Suctionaid®, BLUperc®, BLUgriggs®
Conformity Assessment Route:	Annex II (excluding Section 4)
Notified Body:	BSI Healthcare Medical Devices Certification Notified Body #2797
EC Certificate Number:	CE 669121

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: 29Jan2020

Name: Stacy Novak

Title: Director, Regulatory Operations

Location of Signatory: Minneapolis, MN US

Appendix 1: Revision History

Revision Number	Summary of Changes / Additions	Created / Revised by	Date
100	Initial Release for NPI PAEDS Project 1559 with FDA edits for home use in IFU; ISO 5366 partial compliance; and Hythe as LM.	Kristen Evenson	25-JUN-2018
101	Corrected Tijuana's address Added BLUselect tracheostomy tubes, BLUselect Suctionaid tracheostomy tubes and BLUselect tracheostomy Inner Cannulas BLUgriggs Percutaneous Dilation Tracheostomy Kits BLUperc Percutaneous Dilation Tracheostomy Kits LM Change from Hythe, UK to Minneapolis, MN US Added Hranice, Czech Republic as a Manufacturing site. Changed Signatory as Donna Semlak is no longer with Smiths Medical.	Kristen Evenson	18-JAN-2019
102	Updated to current DoC template (from 003 to 106), which includes moving the SKUs from Appendix 1 to an attached spreadsheet. Removed Kent Legal Manufacturer address as Smiths Medical ASD, Inc. is the current Legal Manufacturer. 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 notified body number (from 0086 to 2797) as BSI is migrating issued certificates from the UK to the Netherlands due to Brexit. The EC Certificate number remains the same.	Nancy DeAngelo	28-JAN-2020