smiths medical bringing technology to life	**Declaration of Conformity** S1055: Tracheostomy Portex Percutaneous Dilation Kits	DoC-061 Revision Number: 108

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):	Portex®
Product Scope:	Sterile Tracheostomy Tubes and kits
Conformity Assessment Route:	Annex II (excluding Section 4)
Notified Body:	BSI Healthcare Medical Device 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: 2 AUG 2019

Name: Stacy Novak

Title: Sr. Manager, Regulatory Operations

Location of Signatory: Minneapolis, MN, USA

Appendix 1: Product List

Num	Catalog Number	Product Description	Manufacturing Site	UMDNS (if applicable)	GMDN Code	EU Risk Class	EU Rule
1.	100/561/070	PDT KIT WITH 7.0MM BLU TRACHY SINGLE STAGE DILATOR 1/EA	Smiths Medical International Ltd 52 Grayshill Road, Westfield Industrial Estate Cumbernauld, Glasgow G68 9HQ United Kingdom	N/A	14099	IIa	7
2.	100/561/080	PDT KIT WITH 8.0MM BLU TRACHY SINGLE STAGE DILATOR 1/EA	Smiths Medical International Ltd 52 Grayshill Road, Westfield Industrial Estate Cumbernauld, Glasgow G68 9HQ United Kingdom	N/A	14099	IIa	7
3.	100/561/090	PDT KIT WITH 9.0MM BLU TRACHY SINGLE STAGE DILATOR 1/EA	Smiths Medical International Ltd 52 Grayshill Road, Westfield Industrial Estate Cumbernauld, Glasgow G68 9HQ United Kingdom	N/A	14099	IIa	7
4.	100/563/070	ULTRAPERC PDT KIT 7MM 1/CA	Smiths Medical International Ltd 52 Grayshill Road, Westfield Industrial Estate Cumbernauld, Glasgow G68 9HQ United Kingdom	N/A	14099	IIa	7
5.	100/563/080	ULTRAPERC PDT KIT 8mm 1/CA	Smiths Medical International Ltd 52 Grayshill Road, Westfield Industrial Estate Cumbernauld, Glasgow G68 9HQ United Kingdom	N/A	14099	IIa	7
6.	100/563/090	ULTRAPERC PDT KIT 9MM 1/CA	Smiths Medical International Ltd 52 Grayshill Road, Westfield Industrial Estate Cumbernauld, Glasgow G68 9HQ United Kingdom	N/A	14099	IIa	7
7.	100/591/070	TRACH ULTRAPERC SINGLE DILATOR BLU 7.0MM + 1/EA	Smiths Medical International Ltd 52 Grayshill Road, Westfield Industrial Estate Cumbernauld, Glasgow G68 9HQ United Kingdom	N/A	14099	IIa	7

Num	Catalog Number	Product Description	Manufacturing Site	UMDNS (if applicable)	GMDN Code	EU Risk Class	EU Rule
8.	100/591/080	TRACH ULTRAPERC SINGLE DILATOR BLU 8.0MM + 1/EA	Smiths Medical International Ltd 52 Grayshill Road, Westfield Industrial Estate Cumbernauld, Glasgow G68 9HQ United Kingdom	N/A	14099	IIa	7
9.	100/591/090	TRACH ULTRAPERC SINGLE DILATOR BLU 9.0MM + 1/EA	Smiths Medical International Ltd 52 Grayshill Road, Westfield Industrial Estate Cumbernauld, Glasgow G68 9HQ United Kingdom	N/A	14099	IIa	7

Appendix 2: Revision History

Revision Number	Summary of Changes / Additions	Created / Revised by	Date (DD-MMM-YYYY Format)
004	Updated to new format. Combined TF14-03 and TF14-04 DoC documents into one DoC (S1055). Renamed technical files per Global STED requirement. Changed of Approver from Susanna Gustafson to Jim Broughton. Removed obsoleted codes: 100/545/070; 100/545/080; 100/545/090; 100/546/070; 100/546/080; 100/546/090.	Regulatory	MAY-2015
005	Updated DoC to the latest Template, Added part number 100/542/070 which was inadventently missed during the previous format update.	Mitchell Madsen	27-JAN-2017
006	Updated DoC codes 100/561/070, 100/561/080, 100/561/090, 100/563/070, 100/563/080, and 100/563/090 have changed Manufacturing Site from Rossendale to Glasgow	Mitchell Madsen	04-MAY-2017
007	Updated to new template from Rev 002 to Rev 003. 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 S1055 to DoC-061 and revision from 006 to 007 and added STED # to header for traceability to STED. 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, updated to new certificate number from 053 01 A CE to CE 661325 and changed the effective date; changed Medical Devices section on page one from Tracheostomy Portex Percutaneous Dilation Kits to Tracheostomy Tubes to match certificate product scope, changed the EU Risk Class for 100/893/070,100/893/080, 100/893/090 from IIa to IIb as they are Uniperc Percutaneous Dilation Tracheostomy Kit and changed the EU rule from 7 to 8 for those SKU's, Removed 100/540/070, 100/540/080, 100/540/090, 100/542/070, 100/542/080, 100/542/090, 100/541/070, 100/541/080, 100/541/090, 100/543/070, 100/543/080, 100/543/090, 100/547/070, 100/547/080, 100/547/090, 100/548/070, 100/548/080, 100/548/090, 100/652/000,	Manasa Boppana	14-DEC-2017

Revision Number	Summary of Changes / Additions	Created / Revised by	Date (DD-MMM-YYYY Format)
	100/572/000, 100/891/070, 100/891/080, 100/891/090, 100/893/070 , 100/893/080, 100/893/090, 100/597/070, 100/597/080, 100/597/090, and created a new DoC-072 as they are moved to Czech republic on Rosendale closure where the codes ended with CZ.		
108	Updated to the latest template revision (from 003 to 104). Changed revision from 007 to 108 per revision formatting requirements in DVSOP2005. Changed the Legal Manufacturer from MHYT to MMSP as per FM-DVSOP8005-05. Changed the Product Tradename from "Portex® percutaneous tracheostomy kit" to "Portex®" to reflect the affected SKUs. Changed the Product Scope from "Tracheostomy Tubes" to "Sterile Tracheostomy Tubes and kits" to align with the scoping statement on EC Certificate 669121. 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. Revised the Product Descriptions to match the descriptions in Agile. Revised the Manufacturing Site address for Cumbernauld to match the address listed on EC Certificate 669121.	Thomas Saladin	20-AUG-2019