smiths medical bringing technology to life	**Declaration of Conformity** S1057- Tracheostomy: Portex Inner Cannula Family	DoC-063 Revision Number: 106

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® Tracheostomy Tube Inner Cannula, Portex® UniPerc® Inner Cannula
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.

Reference Attachment 1 for list of affected SKUs.

Authorized Signatory:

Signature: Angela Kilian Date: 28 MAY 2020

Name: Angela Kilian

Title: Director, Regulatory Affairs

Location of Signatory: Minneapolis, MN, USA

Appendix 1: Revision History

Revision Number	Summary of Changes / Additions	Created / Revised by	Date
02	Update to newest template revision, update to latest EC certificate	Breanna Fautsch	09-DEC-2016
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 S1057 to DoC-063 and revision from 02 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 Notified Body name from Intertek to BSI, updated EC Certificate from 053-01 A CE to CE 661325 and removed the Date Issued date. Updated the manufacturing sites from Hythe to Tijuana as Hythe is no longer a manufacturing site. Removed the codes 100/522/070, 100/522/080, 100/522/090, 100/790/070, 100/790/080, and 100/790/090 because they are Inactive and Post Phase Out and cannot be commercially distributed.	Mitchell Madsen	26-OCT-2017
105	-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. The EC Certificate number has changed from CE 661325 to CE 669121. -Revised SKU descriptions to match description field in Agile. -Revised STED Name from "Portex Tracheostomy Inner Cannula" to "Tracheostomy: Portex Inner Cannula" to match the description field in Agile.	Mitchell Madsen/Alicia Wilson	24-JUL-2019

Revision Number	Summary of Changes / Additions	Created / Revised by	Date
	-Changed the Product Scope from "Tracheostomy Tubes" to "Sterile and Non-Sterile Breathing Systems and Circuits" to match the scope on the EC Certificate. -Updated the Tijuana address in the Manufacturing Site column in Appendix 1 to match the Tijuana address on EC Certificate 669121. Added External Reference Number column in Appendix 1 as some SKUs have an external and internal reference number. For 100/850/XXX SKUs, added internal reference numbers (CZ codes) and changed the Manufacturing Site from Tijuana to Hranice to align with current manufacturing activities. The 100/851/XXX SKUs are manufactured in Hranice and Tijuana. The 100/851/XXX are manufactured in Tijuana and the 100/851/XXXCZ are manufactured in Hranice but sold as 101/851/XXX. To show this, the 100/851/XXX SKUs have two lines -- both have 100/851/XXX as the external number but different internal numbers (100/851/XXX or 100/851/XXXCZ). For 100/890/XXX SKUs, added internal reference numbers (CZ codes) and changed the Manufacturing Site from Tijuana to Hranice to align with current manufacturing activities.		
106	Updated the DoC to the latest template in Agile (from rev 106 to 107), which includes moving Appendix 1 SKU list to the Attachment 1 spreadsheet. Assessed the DoC for impact as S1057 and the ERC of S1057 were revised and determined that there is not impact.	Swathi Yelleni	28-MAY-2020

External Reference Number	Internal Reference Number	Product Description	GMDN Code	EU Risk Class	EU Rule
100/850/060	100/850/060CZ	Replacement Inner Cann 6.0mm Plain B/L Ultra	14089	IIb	5
100/850/070	100/850/070CZ	Replacement Inner Cann 7.0mm Plain B/L Ultra	14089	IIb	5
100/850/075	100/850/075CZ	Replacement Inner Cann 7.5mm Plain B/L Ultra	14089	IIb	5
100/850/080	100/850/080CZ	Replacement Inner Cann 8.0mm Plain B/L Ultra	14089	IIb	5
100/850/085	100/850/085CZ	Replacement Inner Cann 8.5mm Plain B/L Ultra	14089	IIb	5
100/850/090	100/850/090CZ	Replacement Inner Cann 9.0mm Plain B/L Ultra	14089	IIb	5
100/850/100	100/850/100CZ	Replacement Inner Cann 10.0mm Plain B/L Ultra	14089	IIb	5
100/851/060	100/851/060	Replacement Inner Cann 6.0mm Fenestrated B/L Ultra	14089	IIb	5
100/851/060	100/851/060CZ				
100/851/070	100/851/070	Replacement Inner Cann 7.0mm Fenestrated B/L Ultra	14089	IIb	5
100/851/070	100/851/070CZ				
100/851/075	100/851/075	Replacement Inner Cann 7.5mm Fenestrated B/L Ultra	14089	IIb	5
100/851/075	100/851/075CZ				
100/851/080	100/851/080	Replacement Inner Cann 8.0mm Fenestrated B/L Ultra	14089	IIb	5
100/851/080	100/851/080CZ				
100/851/085	100/851/085	Replacement Inner Cann 8.5mm Fenestrated B/L Ultra	14089	IIb	5
100/851/085	100/851/085CZ				
100/851/090	100/851/090	Replacement Inner Cann 9.0mm Fenestrated B/L Ultra	14089	IIb	5
100/851/090	100/851/090CZ				
100/851/100	100/851/100	Replacement Inner Cann 10.0mm Fenestrated B/L Ultra	14089	IIb	5
100/851/100	100/851/100CZ				
100/856/060	100/856/060	Replacement Blu Tracheostomy Inner Cannula - Plain, 6.0mm	14089	IIb	5
100/856/070	100/856/070	Replacement Blu Tracheostomy Inner Cannula - Plain, 7.0mm	14089	IIb	5
100/856/075	100/856/075	Replacement Blu Tracheostomy Inner Cannula - Plain, 7.5mm	14089	IIb	5
100/856/080	100/856/080	Replacement Blu Tracheostomy Inner Cannula - Plain, 8.0mm	14089	IIb	5
100/856/085	100/856/085	Replacement Blu Tracheostomy Inner Cannula - Plain, 8.5mm	14089	IIb	5
100/856/090	100/856/090	Replacement Blu Tracheostomy Inner Cannula - Plain, 9.0mm	14089	IIb	5
100/856/100	100/856/100	Replacement Blu Tracheostomy Inner Cannula - Plain, 10.0mm	14089	IIb	5
100/858/060	100/858/060	Replacement Blu Tracheostomy Inner Cannula Plain 6.0mm	14089	IIb	5
100/858/070	100/858/070	Replacement Blu Tracheostomy Inner Cannula Plain 7.0mm	14089	IIb	5

External Reference Number	Internal Reference Number	Product Description	GMDN Code	EU Risk Class	EU Rule
100/858/075	100/858/075	Replacement Blu Tracheostomy Inner Cannula Plain 7.5mm	14089	IIb	5
100/858/080	100/858/080	Replacement Blu Tracheostomy Inner Cannula Plain 8.0mm	14089	IIb	5
100/858/085	100/858/085	Replacement Blu Tracheostomy Inner Cannula Plain 8.5mm	14089	IIb	5
100/858/090	100/858/090	Replacement Blu Tracheostomy Inner Cannula Plain 8.5mm	14089	IIb	5
100/858/100	100/858/100	Replacement Blu Tracheostomy Inner Cannula Plain 10.0mm	14089	IIb	5
100/890/070	100/890/070CZ	Replacement Inner Cannula for Uniperc Adjustable Flange Tracheostomy Tube, 7mm	14089	IIb	5
100/890/080	100/890/080CZ	Replacement Inner Cannula for Uniperc Adjustable Flange Tracheostomy Tube, 8mm	14089	IIb	5
100/890/090	100/890/090CZ	Replacement Inner Cannula for Uniperc Adjustable Flange Tracheostomy Tube, 9mm	14089	IIb	5