

	Declaration of Conformity	DoC-036 Revision Number: 112
	S1030: Intubation Systems: Introducers, Guides and Stylets	

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): Premium™ disposable anaesthesia face mask
Premium Plus™ disposable anaesthesia face mask

Product Scope: Intubation Systems Accessories

Conformity Assessment Route: Annex V

Notified Body: BSI Healthcare
Medical Devices Certification
Notified Body #2797

EC Certificate Number: CE 685113

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: 26 Jul 2019

Name: Stacy Novak

Title: Sr. Manager, Regulatory Operations

Location of Signatory: Minneapolis, MN, USA

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Appendix 1: Product List

Num	Catalog Number	Product Description	Manufacturing Site	UMDNS	GMDN Code	EU Risk Class	EU Rule
1.	100/120/100	TRACHEAL INTUBATION STYLET LENGTH 255MM 10/BX	Smiths Healthcare Manufacturing SA de CV Carretera Miguel Aleman Km 21.7 Parque Industrial Monterrey Apodaca NL CP 66603 Mexico	N/A	37469	Is	5
2.	100/120/200	TRACHEAL INTUBATION STYLET LENGTH 335MM 10/BX	Smiths Healthcare Manufacturing SA de CV Carretera Miguel Aleman Km 21.7 Parque Industrial Monterrey Apodaca NL CP 66603 Mexico	N/A	37469	Is	5
3.	100/120/300	TRACHEAL INTUBATION STYLET LENGTH 365MM 10/BX	Smiths Healthcare Manufacturing SA de CV Carretera Miguel Aleman Km 21.7 Parque Industrial Monterrey Apodaca NL CP 66603 Mexico	N/A	37469	Is	5
4.	100/121/200	INTUB STYLET B/L TRACH TYP B10 10/BX	Smiths Healthcare Manufacturing SA de CV Carretera Miguel Aleman Km 21.7 Parque Industrial Monterrey Apodaca NL CP 66603 Mexico	N/A	37469	Is	5
5.	100/121/300	INTUB STYLET B/L TRACH LONG B10 10/BX	Smiths Healthcare Manufacturing SA de CV Carretera Miguel Aleman Km 21.7 Parque Industrial Monterrey Apodaca NL CP 66603 Mexico	N/A	37469	Is	5
6.	100/123/015	PORTEX EXCHANGE GUIDE, 15FR 10/BX	Smiths Healthcare Manufacturing SA de CV Carretera Miguel Aleman Km 21.7 Parque Industrial Monterrey Apodaca NL CP 66603 Mexico	N/A	37469	Is	5
7.	100/123/515	PORTEX SINGLE USE BOUGIE + 10/BX	Smiths Healthcare Manufacturing SA de CV Carretera Miguel Aleman Km 21.7 Parque Industrial Monterrey Apodaca NL CP 66603 Mexico	N/A	41829	Is	5

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Num	Catalog Number	Product Description	Manufacturing Site	UMDNS	GMDN Code	EU Risk Class	EU Rule
8.	100/125/005	PORTEX TRACHEAL TUBE GUIDE SINGLE USE BOUGIE SIZE 5CH 10/BX	Smiths Healthcare Manufacturing SA de CV Carretera Miguel Aleman Km 21.7 Parque Industrial Monterrey Apodaca NL CP 66603 Mexico	N/A	42084	Is	5
9.	100/125/010	PORTEX TRACHEAL TUBE GUIDE 10CH (SINGLE USE)_ 10/BX	Smiths Healthcare Manufacturing SA de CV Carretera Miguel Aleman Km 21.7 Parque Industrial Monterrey Apodaca NL CP 66603 Mexico	N/A	42084	Is	5

Appendix 2: Revision History

Revision Number	Summary of Changes / Additions	Created / Revised by	Date (DD-MMM-YYYY Format)
005	Updating DoC to the latest Template, Update EC Cert Info	Mitchell Madsen	06-JAN-2017
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 S1030 to DoC-036 and revision from 005 to 006 and added STED # to header for traceability to STED.	Stacy Novak	31-MAY-2017
007	Removed product codes 100/123/015, 100/125/005, and 100/125/010 as these were codes for marketing literature. Included product category from CE certificate "Intubation Systems". Removed Annex VII from DoC as it is not applicable	Stacy Novak	27-JUN-2017
008	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 and updated to new revision from 007 to 008.	Manasa Boppana	26-JULY-2017
009	Updated to next revision, changed the effective date, Authorized signatory and removed the SKU's 14-504-17, 14-504-68 and 14-504-76 and added to Doc-184 as they are class Ins/nm and are self-certified	Manasa Boppana	04-OCT-2017

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Revision Number	Summary of Changes / Additions	Created / Revised by	Date (DD-MMM-YYYY Format)
010	Updated DoC to the latest Template in Agile. Added the following codes (100/123/015, 100/125/005, and 100/125/010) back onto the DoC as they were inadvertently removed on revision 007 which stated they were removed due to the fact that they were indicated as "marketing literature" in Smiths Medical document management system when they were actually Finished Good SKUs. Corrected Product Descriptions to correspond with labeling for all product codes on DoC.	Mitchell Madsen	04-JAN-2018
111	Update FM-DVDP1509-01 template to Revision 003. Update to revision 111 to correspond to same revision as EU STED S1030, DoC-036 and ERC-S1030 and per DVSOP2005 which states that items must be at 100 for production release. No revisions were skipped. The manufacturing site address was changed (the zip code was incorrect) for Customer Inquiry 16413.	Kristen Evenson	15-OCT-2018
112	-Changed the template from rev 003 to rev 104. Changed the DoC revision from 111 to 112. Changed formatting by unmerging cells in Appendix 1. -Changed STED title from "Portex Stylets, Bougies and Exchange Guides" to "Intubation Systems: Introducers, Guides and Stylets" to match current title. -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. -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 661328 to CE 685113 due to the Legal Manufacturer change. -Updated the Product Scope from "Intubation Systems" to "Intubation Systems Accessories."	Mitchell Madsen	18-JUL-2019

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Revision Number	Summary of Changes / Additions	Created / Revised by	Date (DD-MMM-YYYY Format)
	-Changed the Authorized Signatory from Donna Semlak to Stacy Novak. -Updated the Monterrey address in the Manufacturing Site column in Appendix 1 to match the address listed on the EC Certificate.		