

	Declaration of Conformity	DoC-156 Revision number: 107
	S1225: SecureEasy, Masks, Airways and Mouthpieces	

Manufacturer: Smiths Medical ASD, Inc.
6250 Shier Rings Road
Dublin, Ohio 43016, United States

EU Representative: Smiths Medical International, Ltd.
1500 Eureka Park, Lower Pemberton
Ashford, Kent TN25 4BF, UK

Product Tradename(s): Portex, SecureEasy® endotracheal tube holder, Quickstrap® endotracheal tube holders

Product Scope: Intubation

Conformity Assessment Route: Annex VII

Notified Body: N/A

EC Certificate Number: N/A

Start of CE-Marking: MAY, 2004

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: 25 June 2011

Name: Stacy Novak

Title: Sr. Manager, Regulatory Operations

Location of Signatory: Minneapolis, MN USA

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Appendix 1: Product List

Num	Product Code	Product Description	Manufacturing Site	UMDNS (if applicable)	GMDN Code	EU Risk Class	EU Rule
1.	242003	SECUREEASY@ENDOTRACHEAL TUBE HOLDER	Smiths Healthcare Manufacturing SA de CV Main site: Carretera Miguel Aleman Km 21.7, Parque Industrial Monterrey, Apodaca NL CP 666003 Mexico	N/A	35815	Ins	1
2.	242006	SECUREEASY@ENDOTRACHEAL TUBE HOLDER	Smiths Healthcare Manufacturing SA de CV Main site: Carretera Miguel Aleman Km 21.7, Parque Industrial Monterrey, Apodaca NL CP 666003 Mexico	N/A	35815	Ins	1
3.	242007	QUICKSTRAP(TM) ENDOTRACH TUBE HOLDER	Smiths Healthcare Manufacturing SA de CV Main site: Carretera Miguel Aleman Km 21.7, Parque Industrial Monterrey, Apodaca NL CP 666003 Mexico	N/A	35815	Ins	1
4.	242008	QUICKSTRAP(TM) NECK STRAP	Smiths Healthcare Manufacturing SA de CV Main site: Carretera Miguel Aleman Km 21.7, Parque Industrial Monterrey, Apodaca NL CP 666003 Mexico	N/A	35815	Ins	1
5.	242010	QUICKSTRAP(TM) ENDOTRACH TUBE HOLDER	Smiths Healthcare Manufacturing SA de CV Main site: Carretera Miguel Aleman Km 21.7, Parque Industrial Monterrey, Apodaca NL CP 666003 Mexico	N/A	35815	Ins	1
6.	242024	SECUREEASY@ NECK STRAP	Smiths Healthcare Manufacturing SA de CV Main site: Carretera Miguel Aleman Km 21.7, Parque Industrial Monterrey, Apodaca NL CP 666003 Mexico	N/A	35815	Ins	1

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Appendix 2: Revision History

Revision Number	Summary of Changes / Additions	Created / Revised by	Date (DD-MMM-YYYY Format)
006	Converted document to Revision 002 format. Left out notified body address for consistency between DoCs. 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 S1225 to DoC-156 and revision from 005 to 006 and added STED # to header for traceability to STED. Remove Product Codes (2018, 2020, 2025, 2026, 2027 and 2028) that are inactive products no longer manufactured. Added columns "Group on EC Certificate Annex II, UMDNS, GIVD and IVD Classification" as they are a part of the DoC Rev 002 template.	Stacy Novak	21-JUN-2017
107	Updated template to latest revision (from 002 to 104). Removed "SGS United Kingdom Ltd. Notified Body #0120" from the Notified Body section as this is an Annex VII DoC with self-certified products. As a result, a Notified Body is not required. Unmerged cells in Appendix 1 for easier reading and editing. Added tradenames (Portex, SecureEasy® endotracheal tube holder, Quickstrap® endotracheal tube holders) based on the affected SKUs' labeling. Added Product Scope (Intubation) based on the affected SKUs' product family. Added Start of CE Marking as "MAY, 2004" based on date from the first revision of TFRP-009 (previous tech file). Removed 2007 as it's inactive/post-phout and on CR-OBS-10001149 in Obsolescence Execution Status. Removed 242091 as it's inactive/post-phout and on CR-OBS-10001021 in Obsolescence Execution Status.	Alicia Wilson	18-JUN-2019

 bringing technology to life	Declaration of Conformity	DoC-156 Revision number: 107
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Revision Number	Summary of Changes / Additions	Created / Revised by	Date (DD-MMM-YYYY Format)
	Assigned GMDN Code 35815 to all SKUs (242003, 242006, 242007, 242008, 242010, and 242024). Confirmed by Kristen Evenson.		