| smiths medical<br>bringing technology to life | **Declaration of Conformity**<br>S1029: Disposable Endotracheal Tube | DoC-035<br>Revision Number: 105 |
|---|---|---|

| | |
|---|---|
| **Legal Manufacturer:** | Smiths Medical ASD, Inc.<br>6000 Nathan Lane North<br>Minneapolis, MN 55442<br>USA |
| **EU Representative:** | Smiths Medical Czech Republic a. s.<br>Olomoucká 306,<br>Hranice 1 - Město,<br>753 01 Hranice, Czech Republic |
| **Product Tradename(s):** | Portex® |
| **Conformity Assessment Route:** | Annex V |
| **Notified Body:** | TUV SUD Product Service GmbH<br>Zertifizierstellen<br>Ridlerstraße 65<br>80339 MÜNCHEN<br>Germany<br>Notified Body #0123 |
| **EC Certificate Number:** | G2 17 04 97063 002 |

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: 28OCT2019

Name: Stacy Novak

Title: Director, Regulatory Operations

Location of Signatory: Minneapolis, MN, US

**Appendix 1: Product List**

| Num | Catalog Number | Product Description | Manufacturing Site | GMDN Code | EU Risk Class | EU Rule |
|---|---|---|---|---|---|---|
| 1. | 100/150/050 | 5mm Portex Tracheal Tube | Jiangsu IAWA Bioscience Engineering Co., Ltd, 211Ji-An Rd,High-Tech Industrial Development Zone, Yangzhou, Jiangsu, China | 46967 | IIa | 5 |
| 2. | 100/150/055 | 5.5mm Portex Tracheal Tube | Jiangsu IAWA Bioscience Engineering Co., Ltd, 211Ji-An Rd, High-Tech Industrial Development Zone, Yangzhou, Jiangsu, China | 46967 | IIa | 5 |
| 3. | 100/150/060 | 6mm Portex Tracheal Tube | Jiangsu IAWA Bioscience Engineering Co., Ltd, 211Ji-An Rd, High-Tech Industrial Development Zone, Yangzhou, Jiangsu, China | 46967 | IIa | 5 |
| 4. | 100/150/065 | 6.5mm Portex Tracheal Tube | Jiangsu IAWA Bioscience Engineering Co., Ltd, 211Ji-An Rd, High-Tech Industrial Development Zone, Yangzhou, Jiangsu, China | 46967 | IIa | 5 |
| 5. | 100/150/070 | 7mm Portex Tracheal Tube | Jiangsu IAWA Bioscience Engineering Co., Ltd, 211Ji-An Rd, High-Tech Industrial Development Zone, Yangzhou, Jiangsu, China | 46967 | IIa | 5 |
| 6. | 100/150/075 | 7.5mm Portex Tracheal Tube | Jiangsu IAWA Bioscience Engineering Co., Ltd, 211Ji-An Rd, High-Tech Industrial Development Zone, Yangzhou, Jiangsu, China | 46967 | IIa | 5 |
| 7. | 100/150/080 | 8mm Portex Tracheal Tube | Jiangsu IAWA Bioscience Engineering Co., Ltd, 211Ji-An Rd, High-Tech Industrial Development Zone, Yangzhou, Jiangsu, China | 46967 | IIa | 5 |

| Num | Catalog Number | Product Description | Manufacturing Site | GMDN Code | EU Risk Class | EU Rule |
|---|---|---|---|---|---|---|
| 8. | 100/150/085 | 8.5mm Portex Tracheal Tube | Jiangsu IAWA Bioscience Engineering Co., Ltd,<br>211Ji-An Rd, High-Tech Industrial Development Zone, Yangzhou, Jiangsu, China | 46967 | IIa | 5 |
| 9. | 100/150/090 | 9mm Portex Tracheal Tube | Jiangsu IAWA Bioscience Engineering Co., Ltd,<br>211Ji-An Rd, High-Tech Industrial Development Zone, Yangzhou, Jiangsu, China | 46967 | IIa | 5 |
| 10. | 100/150/095 | 9.5mm Portex Tracheal Tube | Jiangsu IAWA Bioscience Engineering Co., Ltd,<br>211Ji-An Rd, High-Tech Industrial Development Zone, Yangzhou, Jiangsu, China | 46967 | IIa | 5 |

**Appendix 2: Revision History**

| Revision Number | Summary of Changes / Additions | Created / Revised by | Date |
|---|---|---|---|
| 001 | Transferring information from TF 07-05/02 to Global STED S1029, DoC number changing in accordance with new numbering system. | Kay Friend | 01-OCT-2015 |
| 002 | Changed manufacturer from Hythe to Minneapolis, MN; change Notified Body from Intertek to TUV | Stacy Novak | 02-MAY-2017 |
| 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 S1029 to DoC-035 and revision from 002 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 CE Certificate Number from G1 17 04 97063 002 to G2 17 04 97063 002 to cover the above SKUs with the correct certificate. Changed Authorized Signatory from James Taufen to Stacy Novak. | Mitchell Madsen | 08-DEC-2017 |
| 105 | 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.<br>Updated to latest template revision (from 003 to 105).<br>Added “Portex®” to reflect the tradename of the affected SKUs.<br>Changed product descriptions to match the descriptions in Agile.<br>Changed the STED title from “Breathing Systems – Endotracheal Tubes” to “Disposable Endotracheal Tube” to match the description in Agile.<br>Revised the Manufacturing Site address for Jiangsu IAWA Bioscience Engineering Co., Ltd, to match the address listed in S1029. | Madi Johnson | 24-OCT-2019 |