| smiths medical<br>bringing technology to life | **Declaration of Conformity**<br>S1177: Regional Anaesthesia | DoC-175<br>Revision Number: 110 |
|---|---|---|

| | |
|---|---|
| **Manufacturer:** | Smiths Medical ASD, Inc<br>6000 Nathan Lane North<br>Minneapolis, Minnesota 55442 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® LOCKIT PLUS® |
| **Product Scope:** | Sterile Regional anaesthesia locks, specimen trap, securement and laryngotracheal Kit |
| **Conformity Assessment Route:** | Annex V |
| **Notified Body:** | BSI Healthcare<br>Medical Devices Certification<br>Notified Body #2797 |
| **EC Certificate Number:** | CE 685113 |
| **Start of CE-Marking:** | MAR, 2016 |

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: 23 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. | F031-61 | LARYNGOTRACHEAL ANAESTHESTIA KIT | Smiths Medical ASD Inc. 10 Bowman Drive Keene, NH 03431 USA | N/A | 46382 | Is | 5 |
| 2. | 100/399/216 | LOCKIT PLUS 16/17G | Smiths Medical ASD Inc. 10 Bowman Drive Keene, NH 03431 USA | N/A | 34864 | Is | 4 |
| 3. | 100/399/218 | 18G LOCKIT PLUS REGIONAL ANAESCATHETER SECUREMENT DEVICE | Smiths Medical ASD Inc. 10 Bowman Drive Keene, NH 03431 USA | N/A | 34864 | Is | 4 |

**Appendix 2: Revision History**

| Revision Number | Summary of Changes / Additions | Created / Revised by | Date (DD-MMM-YYYY Format) |
|---|---|---|---|
| 001 | Initial Release. Removed table of Class Is product and retained Annex V product from DoC-127 and created new DoC# 175. Updated table to reflect current version of DoC template (added UMDNS, GIVD and IVD Classification columns). | Brent Pearson | 05-SEP-2017 |
| 109 | Updated the DoC to the latest template in Agile from Rev 002 to 003. Changed the Authorized Signatory from James Taufen to Sunita Teekasingh. Changed the Product Scope from Regional Anaesthesia Accessories to Regional Anaesthesia Devices. Made formatting changes in Appendix 1 such as unmerging cells, changing alignments and filling in blank cells that were previously merged. Changed the GMDN code for the codes 100/399/216 and 100/399/218 from 34916 to 34864. Updated the Product Descriptions for the codes 100/399/216 and 100/399/218 to reflect the descriptions on the marketing literature.<br><br>Changed revision format from “00X” to “1XX” due to update of DVSOP2005 which requires document revisions to be in the “1XX” format; there are no missing revisions for this DoC (i.e. rev 002 - rev 108). These revisions were skipped to align with the STED and ERC so that all three documents are at the same revision which is revision 109. | Mitchell Madsen | 05-OCT-2018 |
| 110 | Updated to latest template revision (from 003 to 104).<br>Changed the legal manufacturer from MKEE to MMSP as per FM-DVSOP8005-05.<br>Changed the Product Tradename(s) from "LOCKIT PLUS™ Regional Anesthesia Catheter Securement Device and Laryngotracheal Anaesthesia Kit" to "Portex® LOCKIT PLUS®" to better reflect the affect SKU's tradenames.<br>Changed the Product Scope from "Regional Anaesthesia Devices" to "Sterile Regional anaesthesia locks, specimen | Thomas Saladin | 22-AUG-2019 |

| Revision Number | Summary of Changes / Additions | Created / Revised by | Date (DD-MMM-YYYY Format) |
|---|---|---|---|
| | trap, securement and laryngotracheal Kit" to align with the scoping statement on EC Certificate 685113<br>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>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 CE 660826 to CE 685113 due to the Legal Manufacturer change.<br>Removed 932/000/0563 and 934/000/0004 as these SKUs are inactive in Agile and post-phase out in Oracle.<br>Revised the Product Descriptions to match the descriptions in Agile.<br>Revised the Manufacturing Site address for Keene to match the address listed on EC Certificate 660826.<br>Changed the GMDN Code for F031-61 from 35905 to 46382 as 35905 was obsoleted by the GMDN Agency. | | |