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|  | <b>Declaration of Conformity</b>    | DoC-256<br>Revision Number: 102 |
|                                                                                   | S1257: Arterial Blood Sampling Kits |                                 |

**Legal Manufacturer:**

Smiths Medical ASD, Inc.  
 6000 Nathan Lane N.  
 Minneapolis, MN 55442 USA

**EU Representative:**

Smiths Medical Czech Republic a.s.  
 Olomoucká 306,  
 Hranice 1 - Město,  
 753 01 Hranice, Czech Republic

**Product Tradename(s):**

LineDraw™ arterial blood gas sampling syringe, Pro-Vent® arterial blood sampling kit, Pulsator® arterial blood sampling kit

**Conformity Assessment Route:**

MDD Annex II (excluding Section 4), IVDD Annex III

**Notified Body:**

BSI Healthcare  
 Medical Devices Certificate  
 Notified Body # 2797

NA for IVD products

**EC Certificate Number:**

CE 669121, NA for IVD products

Smiths Medical ASD, Inc. hereby declares under its sole responsibility that the product(s) referenced in Appendix 1 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.

Smiths Medical ASD, Inc. hereby declares under its sole responsibility that the product(s) referenced in that the products listed in Appendix 2 conform with the relevant provisions of European Union Council Directive 98/79/EC concerning In Vitro Diagnostic Medical Devices as transposed into national regulations and by subsequent Directives, laws, and other national regulations.

**Authorized Signatory:**

Signature:

*Angela Kilian*

Date: 13 SEP 2019

Name: Angela Kilian

Title: Director, Regulatory Affairs

Location of Signatory: Minneapolis, MN USA

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|                                                                                   | S1257: Arterial Blood Sampling Kits |                                 |

## Appendix 1: MDD Product List

| Num | Catalog Number | Product Description                                                      | Manufacturing Site                                                            | GMDN Code | EU Risk Class | EU Rule |
|-----|----------------|--------------------------------------------------------------------------|-------------------------------------------------------------------------------|-----------|---------------|---------|
| 1.  | 4080PE         | Dry Lithium, 3ml, 23g x 1, P, Needle-Pro                                 | Smiths Medical ASD, Inc.<br>10 Bowman Drive Keene,<br>New Hampshire 03431 USA | 58095     | Ila           | 6       |
| 2.  | 4080PG         | Dry Lithium, 3ml, 23g x 1 EDGE, Pro                                      | Smiths Medical ASD, Inc.<br>10 Bowman Drive Keene,<br>New Hampshire 03431 USA | 58095     | Ila           | 6       |
| 3.  | 4558PE         | Pro-Vent, Dry Lithium, 3ml UI, 23g x 1 Needle                            | Smiths Medical ASD, Inc.<br>10 Bowman Drive Keene,<br>New Hampshire 03431 USA | 58095     | Ila           | 6       |
| 4.  | 4590PG         | PRO-VENT PLUS, 3CC LL SYRINGE, 22G X 1IN NEEDLE, FILTER + EDGE 200/CA    | Smiths Medical ASD, Inc.<br>10 Bowman Drive Keene,<br>New Hampshire 03431 USA | 58095     | Ila           | 6       |
| 5.  | 4619PG         | PRO-VENT PLUS, 1CC SLIP SYRINGE 25G X 5/8IN NEEDLE, FILTER + EDGE 200/CA | Smiths Medical ASD, Inc.<br>10 Bowman Drive Keene,<br>New Hampshire 03431 USA | 58095     | Ila           | 6       |
| 6.  | 4629PG         | PRO-VENT PLUS, 1CC SLIP SYRINGE, 23G X 1IN NEEDLE, FILTER + EDGE 200/CA  | Smiths Medical ASD, Inc.<br>10 Bowman Drive Keene,<br>New Hampshire 03431 USA | 58095     | Ila           | 6       |
| 7.  | 4645PG         | PRO-VENT PLUS, 3CC SLIP SYRINGE 22G X 1IN NEEDLE, FILTER + EDGE 200/CA   | Smiths Medical ASD, Inc.<br>10 Bowman Drive Keene,<br>New Hampshire 03431 USA | 58095     | Ila           | 6       |
| 8.  | 4698PG         | PRO-VENT PLUS, 3CC SLIP SYRINGE, 23G X 1IN NEEDLE, FILTER + EDGE 200/CA  | Smiths Medical ASD, Inc.<br>10 Bowman Drive Keene,<br>New Hampshire 03431 USA | 58095     | Ila           | 6       |
| 9.  | 4558PG         | PRO-VENT PLUS, 3CC LL SYRINGE, 23G X 1IN NEEDLE, FILTER + EDGE 200/CA    | Smiths Medical ASD, Inc.<br>10 Bowman Drive Keene,<br>New Hampshire 03431 USA | 58095     | Ila           | 6       |
| 10. | 910/400/340    | PULSATOR 20G X 1.5IN NEEDLE 3ML LUER LOCK 100/CA                         | Smiths Medical ASD, Inc.<br>10 Bowman Drive Keene,<br>New Hampshire 03431 USA | 58092     | Ila           | 6       |
| 11. | 910/400/380    | PULSATOR 22G X 1IN NEEDLE 3ML LUER LOCK 100/CA                           | Smiths Medical ASD, Inc.<br>10 Bowman Drive Keene,<br>New Hampshire 03431 USA | 58092     | Ila           | 6       |
| 12. | 910/400/380G   | PULSATOR PLUS, 3CC LL SYRINGE 22G X 1IN NEEDLE, FILTER + EDGE            | Smiths Medical ASD, Inc.<br>10 Bowman Drive Keene,<br>New Hampshire 03431 USA | 58092     | Ila           | 6       |

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|                                                                                   | S1257: Arterial Blood Sampling Kits |                                 |

| Num | Catalog Number | Product Description                                                         | Manufacturing Site                                                            | GMDN Code | EU Risk Class | EU Rule |
|-----|----------------|-----------------------------------------------------------------------------|-------------------------------------------------------------------------------|-----------|---------------|---------|
| 13. | 910/400/385    | PULSATOR 22G X 1IN NEEDLE 3ML LUER SLIP 100/CA                              | Smiths Medical ASD, Inc.<br>10 Bowman Drive Keene,<br>New Hampshire 03431 USA | 58092     | Ila           | 6       |
| 14. | 910/400/385G   | PULSATOR PLUS, 3CC LL SYRINGE 22G X 1IN NEEDLE, FILTER + EDGE               | Smiths Medical ASD, Inc.<br>10 Bowman Drive Keene,<br>New Hampshire 03431 USA | 58092     | Ila           | 6       |
| 15. | 910/401/380    | PULSATOR 22G X 1IN NEEDLE (NO BLOCK) 3ML100/CA                              | Smiths Medical ASD, Inc.<br>10 Bowman Drive Keene,<br>New Hampshire 03431 USA | 58092     | Ila           | 6       |
| 16. | 910/401/385    | PULSATOR 22G X 1IN NEEDLE (NO BLOCK) 3ML LUER SLIP 100/CA                   | Smiths Medical ASD, Inc.<br>10 Bowman Drive Keene,<br>New Hampshire 03431 USA | 58092     | Ila           | 6       |
| 17. | 4618PE         | PRO-VENT PLUS,1CC L/S SYRINGE 25G X 5/8IN NEEDLE, FILTER-PRO 200/CA         | Smiths Medical ASD, Inc.<br>10 Bowman Drive Keene,<br>New Hampshire 03431 USA | 58095     | Ila           | 6       |
| 18. | 4619PE         | PRO-VENT PLUS,1CC SYRINGE 25G X 5/8IN NEEDLE, FILTER + NEEDLE-PRO 200/CA    | Smiths Medical ASD, Inc.<br>10 Bowman Drive Keene,<br>New Hampshire 03431 USA | 58095     | Ila           | 6       |
| 19. | 4648PE         | PRO-VENT PLUS, 3CC L/S SYRINGE 22G X 1IN NEEDLE, FILTER-PRO 200/CA          | Smiths Medical ASD, Inc.<br>10 Bowman Drive Keene,<br>New Hampshire 03431 USA | 58095     | Ila           | 6       |
| 20. | 4698PE         | PRO-VENT PLUS, 3CC L/S SYRINGE 23G X 1IN NEEDLE, FILTER + NEEDLE-PRO 200/CA | Smiths Medical ASD, Inc.<br>10 Bowman Drive Keene,<br>New Hampshire 03431 USA | 58095     | Ila           | 6       |
| 21. | 4628PE         | PRO-VENT PLUS,1CC SYRINGE 23G X 1IN NEEDLE, FILTER-PRO 200/CA               | Smiths Medical ASD, Inc.<br>10 Bowman Drive Keene,<br>New Hampshire 03431 USA | 58095     | Ila           | 6       |
| 22. | 4645PE         | PRO-VENT PLUS, 3CC L/S SYRINGE 22G X 1IN NEEDLE, FILTER + NEEDLE-PRO 200/CA | Smiths Medical ASD, Inc.<br>10 Bowman Drive Keene,<br>New Hampshire 03431 USA | 58095     | Ila           | 6       |
| 23. | 4629PE         | PRO-VENT PLUS,1CC L/S SYRINGE 23G X 1IN NEEDLE, FILTER + NEEDLE-PRO 200/CA  | Smiths Medical ASD, Inc.<br>10 Bowman Drive Keene,<br>New Hampshire 03431 USA | 58095     | Ila           | 6       |
| 24. | G1689          | 3ML PRO-VENT SYRINGE 25G X 5/8IN NEEDLE & FILTER-PRO 200/CA                 | Smiths Medical ASD, Inc.<br>10 Bowman Drive Keene,<br>New Hampshire 03431 USA | 58095     | Ila           | 6       |

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| Num | Catalog Number | Product Description                                                      | Manufacturing Site                                                            | GMDN Code | EU Risk Class | EU Rule |
|-----|----------------|--------------------------------------------------------------------------|-------------------------------------------------------------------------------|-----------|---------------|---------|
| 25. | 4658PE         | PRO-VENT PLUS, 3CC L/S SYRINGE<br>23G X 1IN NEEDLE, FILTER-PRO<br>200/CA | Smiths Medical ASD, Inc.<br>10 Bowman Drive Keene,<br>New Hampshire 03431 USA | 58095     | Ila           | 6       |

## Appendix 2: IVDD Product List

| Num | Catalog Number | Product Description                                                     | Manufacturing Site                                                            | GMDN Code | EU Risk Class | EU Rule |
|-----|----------------|-------------------------------------------------------------------------|-------------------------------------------------------------------------------|-----------|---------------|---------|
| 26. | 4616E          | PRO-VENT PLUS, 1CC L/S SYRINGE NO<br>NEEDLE, FILTER-PRO 200/CA          | Smiths Medical ASD, Inc.<br>10 Bowman Drive Keene,<br>New Hampshire 03431 USA | 57894     | General IVD   | N/A     |
| 27. | 4660P-1        | ABG –Provent 3ml LI 100/CA                                              | Smiths Medical ASD, Inc.<br>10 Bowman Drive Keene,<br>New Hampshire 03431 USA | 57894     | General IVD   | N/A     |
| 28. | 910/400/360    | PULSATOR NO NEEDLE 3ML LUER<br>LOCK 100/CA                              | Smiths Medical ASD, Inc.<br>10 Bowman Drive Keene,<br>New Hampshire 03431 USA | 45267     | General IVD   | N/A     |
| 29. | 910/400/365    | PULSATOR NO NEEDLE 3ML LUER SLIP<br>100/CA                              | Smiths Medical ASD, Inc.<br>10 Bowman Drive Keene,<br>New Hampshire 03431 USA | 45267     | General IVD   | N/A     |
| 30. | 4041E          | LINE DRAW, DRY HEPARIN, 1CC<br>SYRINGE, LUER SLIP, FILTER-PRO<br>200/CA | Smiths Medical ASD, Inc.<br>10 Bowman Drive Keene,<br>New Hampshire 03431 USA | 57894     | General IVD   | N/A     |
| 31. | 4042E          | LINE DRAW, DRY HEPARIN, 3CC<br>SYRINGE, LUER LOCK, FILTER-PRO<br>200/CA | Smiths Medical ASD, Inc.<br>10 Bowman Drive Keene,<br>New Hampshire 03431 USA | 57894     | General IVD   | N/A     |
| 32. | 4043E          | LINE DRAW PLUS DRY 3CC SYRINGE<br>LUER SLIP, FILTER-PRO 200/CA          | Smiths Medical ASD, Inc.<br>10 Bowman Drive Keene,<br>New Hampshire 03431 USA | 57894     | General IVD   | N/A     |
| 33. | G1494          | ABG-LINEDRAW 3ML LI M 200/CA                                            | Smiths Medical ASD, Inc.<br>10 Bowman Drive Keene,<br>New Hampshire 03431 USA | 57894     | General IVD   | N/A     |
| 34. | 4646E          | PRO-VENT PLUS, 3CC L/S SYRINGE, NO<br>NEEDLE, FILTER-PRO 200/CA         | Smiths Medical ASD, Inc.<br>10 Bowman Drive Keene,<br>New Hampshire 03431 USA | 57894     | General IVD   | N/A     |

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| Num | Catalog Number | Product Description                                                                 | Manufacturing Site                                                            | GMDN Code | EU Risk Class | EU Rule |
|-----|----------------|-------------------------------------------------------------------------------------|-------------------------------------------------------------------------------|-----------|---------------|---------|
| 35. | 4046E          | PULSATOR PLUS DRY 3CC SYRINGE<br>LUER LOCK, NEEDLE BLOCK CUBE,<br>FILTER-PRO 200/CA | Smiths Medical ASD, Inc.<br>10 Bowman Drive Keene,<br>New Hampshire 03431 USA | 57894     | General IVD   | N/A     |
| 36. | 4041LH         | ABG 1 ML LINE DRAW 7 IU HEPARIN<br>DRY LITHIUM 200/CA                               | Smiths Medical ASD, Inc.<br>10 Bowman Drive Keene,<br>New Hampshire 03431 USA | 57894     | General IVD   | N/A     |
| 37. | 4042LH         | ABG-LINE DRAW 3 ML LL 21 IU HEPARIN<br>DRY LITHIUM 200/CA                           | Smiths Medical ASD, Inc.<br>10 Bowman Drive Keene,<br>New Hampshire 03431 USA | 57894     | General IVD   | N/A     |
| 38. | 4698LH         | ABG-PROVENT 3ML LS 21 IU HEPARIN<br>DRY LITHIUM 200/CA                              | Smiths Medical ASD, Inc.<br>10 Bowman Drive Keene,<br>New Hampshire 03431 USA | 57894     | General IVD   | N/A     |
| 39. | 4619LH         | ABG-PROVENT 1ML LS 7 IU HEPARIN<br>DRY LITHIUM 200/CA                               | Smiths Medical ASD, Inc.<br>10 Bowman Drive Keene,<br>New Hampshire 03431 USA | 57894     | General IVD   | N/A     |

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|                                                                                   | S1257: Arterial Blood Sampling Kits |                                 |

### Appendix 3: Revision History

| Revision Number | Summary of Changes / Additions                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | Created / Revised by | Date        |
|-----------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|-------------|
| 100             | Initial release of DoC-256 for Arterial Blood Sampling Kits                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | Manasa Boppana       | 24-Oct-2018 |
| 101             | Update DoC to reflect compliance to both the MDD and IVDD respectively to devices which contain needles and those which do not. Appendix 2 added to indicate those devices which are IVD. Updated GMDN term from 31336 to 57894, 45267, 58095, and 58092 where appropriate depending upon device type and heparin type used. Updated EU representative to reflect the Hranice site address. Notified Body BSI updated from UK #0086 to NL #2797. Legal Manufacturer updated to Minneapolis site to reflect Legal Consolidation activities. As part of legal consolidation, EC 669121 certificate added to support MDD products listed in Appendix 1. | Dominique Neisz      | 15-AUG-2019 |
| 102             | Updated to latest revision template (from 104 to 105). Administrative correction to remove the following duplicated SKU's from the DoC:<br>910/400/340, 910/400/380, 910/400/385, 910/401/380, 910/401/385, 910/400/360, 910/400/365                                                                                                                                                                                                                                                                                                                                                                                                                 | Dominique Neisz      | 11-SEP-2019 |