	Declaration of Conformity	DoC-256 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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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. 10 Bowman Drive Keene, New Hampshire 03431 USA	58095	Ila	6
2.	4080PG	Dry Lithium, 3ml, 23g x 1 EDGE, Pro	Smiths Medical ASD, Inc. 10 Bowman Drive Keene, New Hampshire 03431 USA	58095	Ila	6
3.	4558PE	Pro-Vent, Dry Lithium, 3ml UI, 23g x 1 Needle	Smiths Medical ASD, Inc. 10 Bowman Drive Keene, 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. 10 Bowman Drive Keene, 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. 10 Bowman Drive Keene, 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. 10 Bowman Drive Keene, 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. 10 Bowman Drive Keene, 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. 10 Bowman Drive Keene, 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. 10 Bowman Drive Keene, 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. 10 Bowman Drive Keene, 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. 10 Bowman Drive Keene, 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. 10 Bowman Drive Keene, New Hampshire 03431 USA	58092	Ila	6

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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. 10 Bowman Drive Keene, 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. 10 Bowman Drive Keene, New Hampshire 03431 USA	58092	Ila	6
15.	910/401/380	PULSATOR 22G X 1IN NEEDLE (NO BLOCK) 3ML100/CA	Smiths Medical ASD, Inc. 10 Bowman Drive Keene, 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. 10 Bowman Drive Keene, 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. 10 Bowman Drive Keene, 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. 10 Bowman Drive Keene, 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. 10 Bowman Drive Keene, 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. 10 Bowman Drive Keene, 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. 10 Bowman Drive Keene, 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. 10 Bowman Drive Keene, 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. 10 Bowman Drive Keene, 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. 10 Bowman Drive Keene, 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 23G X 1IN NEEDLE, FILTER-PRO 200/CA	Smiths Medical ASD, Inc. 10 Bowman Drive Keene, 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 NEEDLE, FILTER-PRO 200/CA	Smiths Medical ASD, Inc. 10 Bowman Drive Keene, New Hampshire 03431 USA	57894	General IVD	N/A
27.	4660P-1	ABG –Provent 3ml LI 100/CA	Smiths Medical ASD, Inc. 10 Bowman Drive Keene, New Hampshire 03431 USA	57894	General IVD	N/A
28.	910/400/360	PULSATOR NO NEEDLE 3ML LUER LOCK 100/CA	Smiths Medical ASD, Inc. 10 Bowman Drive Keene, New Hampshire 03431 USA	45267	General IVD	N/A
29.	910/400/365	PULSATOR NO NEEDLE 3ML LUER SLIP 100/CA	Smiths Medical ASD, Inc. 10 Bowman Drive Keene, New Hampshire 03431 USA	45267	General IVD	N/A
30.	4041E	LINE DRAW, DRY HEPARIN, 1CC SYRINGE, LUER SLIP, FILTER-PRO 200/CA	Smiths Medical ASD, Inc. 10 Bowman Drive Keene, New Hampshire 03431 USA	57894	General IVD	N/A
31.	4042E	LINE DRAW, DRY HEPARIN, 3CC SYRINGE, LUER LOCK, FILTER-PRO 200/CA	Smiths Medical ASD, Inc. 10 Bowman Drive Keene, New Hampshire 03431 USA	57894	General IVD	N/A
32.	4043E	LINE DRAW PLUS DRY 3CC SYRINGE LUER SLIP, FILTER-PRO 200/CA	Smiths Medical ASD, Inc. 10 Bowman Drive Keene, New Hampshire 03431 USA	57894	General IVD	N/A
33.	G1494	ABG-LINEDRAW 3ML LI M 200/CA	Smiths Medical ASD, Inc. 10 Bowman Drive Keene, New Hampshire 03431 USA	57894	General IVD	N/A
34.	4646E	PRO-VENT PLUS, 3CC L/S SYRINGE, NO NEEDLE, FILTER-PRO 200/CA	Smiths Medical ASD, Inc. 10 Bowman Drive Keene, 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 LUER LOCK, NEEDLE BLOCK CUBE, FILTER-PRO 200/CA	Smiths Medical ASD, Inc. 10 Bowman Drive Keene, New Hampshire 03431 USA	57894	General IVD	N/A
36.	4041LH	ABG 1 ML LINE DRAW 7 IU HEPARIN DRY LITHIUM 200/CA	Smiths Medical ASD, Inc. 10 Bowman Drive Keene, New Hampshire 03431 USA	57894	General IVD	N/A
37.	4042LH	ABG-LINE DRAW 3 ML LL 21 IU HEPARIN DRY LITHIUM 200/CA	Smiths Medical ASD, Inc. 10 Bowman Drive Keene, New Hampshire 03431 USA	57894	General IVD	N/A
38.	4698LH	ABG-PROVENT 3ML LS 21 IU HEPARIN DRY LITHIUM 200/CA	Smiths Medical ASD, Inc. 10 Bowman Drive Keene, New Hampshire 03431 USA	57894	General IVD	N/A
39.	4619LH	ABG-PROVENT 1ML LS 7 IU HEPARIN DRY LITHIUM 200/CA	Smiths Medical ASD, Inc. 10 Bowman Drive Keene, New Hampshire 03431 USA	57894	General IVD	N/A

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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: 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