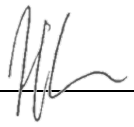
icumedical human connections	**Declaration of Conformity**	DoC-256 Revision Number: 104
	S1257: Arterial Blood Sampling Kits	

Legal Manufacturer:	ICU Medical, Inc. 6000 Nathan Lane North Minneapolis, MN 55442 USA
EU Representative:	ICU Medical B.V. Hofspoor 3 3994 VZ Houten The Netherlands
Product Tradename(s):	LineDraw™ arterial blood sampling kit, 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 Group, The Netherlands B.V. Notified Body # 2797 Not Applicable for IVD products
EC Certificate Number:	CE 669121 (MDD), Not Applicable for IVD products

ICU Medical, Inc. hereby declares under its sole responsibility that the product(s) referenced in Appendix 1 conform to the relevant provisions of Council Directive 93/42/EEC on Medical Devices (the MDD) as amended by Directive 2007/47/EC and the applicable provisions of Article 120 (EU) 2017/745

ICU Medical, 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 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: 

Date: 01-AUG-2025

Name: Jeffrey Wan

Title: Senior Manager, Regulatory Affairs

Location of Signatory: Minneapolis, MN USA

Confidential and Proprietary

Appendix 1: MDD Product List

Num	Catalog Number	Product Description	GMDN Code	EU Risk Class	Rule
1.	4080PE	PULSATOR Arterial Blood Sampling Kit	58095	IIa	6
2.	4080PG	PULSATOR Arterial Blood Sampling Kit	58095	IIa	6
3.	4558PE	PRO-VENT Arterial Blood Sampling Kit	58095	IIa	6
4.	4590PG	PRO-VENT Arterial Blood Sampling Kit	58095	IIa	6
5.	4619PG	PRO-VENT Arterial Blood Sampling Kit	58095	IIa	6
6.	4629PG	PRO-VENT Arterial Blood Sampling Kit	58095	IIa	6
7.	4645PG	PRO-VENT Arterial Blood Sampling Kit	58095	IIa	6
8.	4698PG	PRO-VENT Arterial Blood Sampling Kit	58095	IIa	6
9.	4558PG	PRO-VENT Arterial Blood Sampling Kit	58095	IIa	6
10.	910/400/380G	PULSATOR Arterial Blood Sampling Kit	58092	IIa	6
11.	910/400/385G	PULSATOR Arterial Blood Sampling Kit	58092	IIa	6
12.	4618PE	PRO-VENT Arterial Blood Sampling Kit	58095	IIa	6
13.	4619PE	PRO-VENT Arterial Blood Sampling Kit	58095	IIa	6
14.	4648PE	PRO-VENT Arterial Blood Sampling Kit	58095	IIa	6
15.	4698PE	PRO-VENT Arterial Blood Sampling Kit	58095	IIa	6
16.	4628PE	PRO-VENT Arterial Blood Sampling Kit	58095	IIa	6
17.	4645PE	PRO-VENT Arterial Blood Sampling Kit	58095	IIa	6
18.	4629PE	PRO-VENT Arterial Blood Sampling Kit	58095	IIa	6
19.	G1689	PRO-VENT Arterial Blood Sampling Kit	58095	IIa	6
20.	4658PE	PRO-VENT Arterial Blood Sampling Kit	58095	IIa	6
21.	4698LH	PRO-VENT Arterial Blood Sampling Kit	58095	Iia	6
22.	4619LH	PRO-VENT Arterial Blood Sampling Kit	58095	IIa	6

Appendix 2: IVDD Product List

Num	Catalog Number	Product Description	GMDN Code	EU Risk Class	Rule
23.	4616E	PRO-VENT Arterial Blood Sampling Kit	57894	General IVD	N/A
24.	910/400/360	PULSATOR Arterial Blood Sampling Kit	45267	General IVD	N/A
25.	910/400/365	PULSATOR Arterial Blood Sampling Kit	45267	General IVD	N/A
26.	4041E	LINEDRAW Arterial Blood Sampling Kit	57894	General IVD	N/A
27.	4042E	LINEDRAW Arterial Blood Sampling Kit	57894	General IVD	N/A
28.	4043E	LINEDRAW Arterial Blood Sampling Kit	57894	General IVD	N/A
29.	4646E	PRO-VENT Arterial Blood Sampling Kit	57894	General IVD	N/A
30.	4046E	PULSATOR Arterial Blood Sampling Kit	57894	General IVD	N/A
31.	4041LH	LINEDRAW Arterial Blood Sampling Kit	57894	General IVD	N/A
32.	4042LH	LINEDRAW Arterial Blood Sampling Kit	57894	General IVD	N/A

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
103	Correction to Notified Body Name. Updated EU Representative. Removed SKUs: 910/400/340, 910/400/380, 910/400/385, 910/401/380, 910/401/385, G1494, 4660P-1. Moved SKUs to MDD section and updated GMDN, Risk Class and Rule: 4698LH 4619LH Removed Manufacturing Site column and updated all product descriptions.	Amy Deuchler	18-JUN-2025
104	Updated company logo, name and address to ICU Medical throughout document. Updated footer.	Amy Deuchler	15-JUL-2025