

EC CERTIFICATE

According to Annex II (excluding article 4) of the Directive 93/42/EEC on Medical Devices

Full Quality Assurance System

Certificate Number

CE-MDD-0068/08/2019

Manufacturer : Shunmei Medical Co., Ltd

Address Head Office: : R401 of building B, No.8 of 1st Jinlong Road, Baolong Industrial Zone, Longgang District, Shenzhen 518116, Guangdong, China
Factory : Yifa 3rd road, Yifa Industrial Zone, Pingtan Town, Huiyang District, Huizhou, Guangdong, China

Product(s) : Central Venous Catheter Kit

Model(s) : Please see 2nd and 3rd pages for details of products

Report Number : CE-MED-0068-01

First Issue Date and Place : 22.08.2019 & Istanbul

Revision Number and Date : 00 / --

Validity Date : 06.02.2024

NOTICE, Notified Body 2764, declares that the aforementioned manufacturer has implemented a quality assurance system according to Annex II, Section 3 of the directive 93/42/EEC on medical devices. This quality assurance system covers those aspects of manufacturing concerned with securing and maintaining safe conditions of the respective product(s) and conforms to the provisions of this Directive. The approved quality system is subject to surveillance pursuant to Annex II, Section 5 of Directive 93/42/EEC and unannounced audits. NOTICE must be informed of any significant changes in the design and/or construction of the product(s). This certificate is valid together with Design Certificate issued according to 93/42/EEC Annex II (Section 4) for products defined below.

Özlem Vicdan Akdağ
Chairman



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FR.08.24_Rev.02

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Product Name	No	Specification				
		Model Number	Size	Effective Length (cm)	Lumen	Lumen Flow rate (ml/min)
Central Venous Catheter Kit	1	CVC-01 24G×5cm	24Ga	5	Single	9
	2	CVC-01 24G×8cm		8	Single	7
	3	CVC-01 24G×9cm		9	Single	7
	4	CVC-01 24G×13cm		13	Single	5
	5	CVC-01 24G×15cm		15	Single	4
	6	CVC-01 24G×20cm		20	Single	3
	7	CVC-01 22G×5cm	22Ga	5	Single	13
	8	CVC-01 22G×8cm		8	Single	10
	9	CVC-01 22G×13cm		13	Single	7
	10	CVC-01 22G×15cm		15	Single	6
	11	CVC-01 22G×20cm		20	Single	5
	12	CVC-01 20G×5cm	20Ga	5	Single	15
	13	CVC-01 20G×8cm		8	Single	11
	14	CVC-01 20G×13cm		13	Single	8
	15	CVC-01 20G×15cm		15	Single	7
	16	CVC-01 20G×16cm		16	Single	7
	17	CVC-01 20G×20cm		20	Single	6
	18	CVC-01 18G×12cm	18Ga	12	Single	27
	19	CVC-01 18G×13cm		13	Single	26
	20	CVC-01 18G×15cm		15	Single	24
	21	CVC-01 18G×16cm		16	Single	23
	22	CVC-01 18G×20cm		20	Single	18
	23	CVC-01 17G×20cm	17Ga	20	Single	50
	24	CVC-01 16G×15cm	16Ga	15	Single	85
	25	CVC-01 16G×16cm		16	Single	83
	26	CVC-01 16G×20cm		20	Single	73
	27	CVC-01 16G×30cm		30	Single	60
	28	CVC-01 14G×14cm	14Ga	14	Single	145
	29	CVC-01 14G×15cm		15	Single	140
	30	CVC-01 14G×16cm		16	Single	138
	31	CVC-01 14G×20cm		20	Single	120
	32	CVC-01 14G×30cm		30	Single	110
	33	CVC-01 4F×5cm	4Fr	5	Single	35
	34	CVC-01 4F×10cm		10	Single	30
	35	CVC-01 4F×15cm		15	Single	24
	36	CVC-01 4F×20cm		20	Single	18
	37	CVC-01 4F×25cm		25	Single	14
	38	CVC-01 4F×30cm		30	Single	11
	39	CVC-01 5F×5cm	5Fr	5	Single	120
	40	CVC-01 5F×10cm		10	Single	105
	41	CVC-01 5F×15cm		15	Single	90
	42	CVC-01 5F×20cm		20	Single	80
	43	CVC-01 5F×25cm		25	Single	70
	44	CVC-01 5F×30cm		30	Single	60
	45	CVC-01 8F×5cm	8Fr	5	Single	315
	46	CVC-01 8F×10cm		10	Single	290
	47	CVC-01 8F×15cm		15	Single	275
	48	CVC-01 8F×20cm		20	Single	250
	49	CVC-01 8F×25cm		25	Single	230
	50	CVC-01 8F×30cm		30	Single	215
	51	CVC-02 4F×5cm	4Fr	5	Double	D:24 P: 13
	52	CVC-02 4F×8cm		8	Double	D:18 P: 10
	53	CVC-02 4F×13cm		13	Double	D:12 P: 7
	54	CVC-02 5F×8cm	5Fr	8	Double	D:25 P: 13
	55	CVC-02 5F×10cm		10	Double	D:21 P: 11
	56	CVC-02 5F×13cm		13	Double	D:18 P: 10
	57	CVC-02 5F×15cm		15	Double	D:17 P: 9
	58	CVC-02 5F×16cm		16	Double	D:16 P: 9
	59	CVC-02 5F×20cm		20	Double	D:13 P: 7
	60	CVC-02 7F×15cm	7Fr	15	Double	D:100 P: 55
	61	CVC-02 7F×16cm		16	Double	D:98 P: 53
	62	CVC-02 7F×18cm		18	Double	D:93 P: 48
	63	CVC-02 7F×20cm		20	Double	D:85 P: 45
	64	CVC-02 7F×30cm		30	Double	D:65 P: 30



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2 of 3

Product Name	No	Model Number	Size	Specification			
				Effective Length (cm)	Lumen	Lumen Flow rate (ml/min)	
Central Venous Catheter Kit	65	CVC-02 8F×11cm	8Fr	11	Double	D:115	P: 110
	66	CVC-02 8F×15cm		15	Double	D:110	P: 98
	67	CVC-02 8F×16cm		16	Double	D:108	P: 97
	68	CVC-02 8F×20cm		20	Double	D:105	P: 85
	69	CVC-02 8F×30cm		30	Double	D:90	P: 65
	70	CVC-02 11.5F×5cm	11.5Fr	5	Double	D:290	P: 320
	71	CVC-02 11.5F×10cm		10	Double	D:260	P:280
	72	CVC-02 11.5F×15cm		15	Double	D:250	P: 250
	73	CVC-02 11.5F×20cm		20	Double	D:240	P: 225
	74	CVC-02 11.5F×25cm		25	Double	D:225	P: 205
	75	CVC-02 11.5F×30cm	12Fr	30	Double	D:200	P: 195
	76	CVC-02 12F×5cm		5	Double	D:300	P: 305
	77	CVC-02 12F×10cm		10	Double	D:270	P: 280
	78	CVC-02 12F×15cm		15	Double	D:250	P: 270
	79	CVC-02 12F×20cm		20	Double	D:240	P: 250
	80	CVC-02 12F×25cm		25	Double	D:220	P: 230
	81	CVC-02 12F×30cm		30	Double	D:210	P: 210
	82	CVC-03 4F×5cm	4Fr	5	Triple	D: 30	P: 11 M:11
	83	CVC-03 4F×10cm		10	Triple	D: 24	P: 9 M:9
	84	CVC-03 4F×15cm		15	Triple	D: 19	P: 6 M:6
	85	CVC-03 4F×20cm		20	Triple	D: 17	P: 4 M:4
	86	CVC-03 4F×25cm		25	Triple	D: 14	P: 3 M:3
	87	CVC-03 4F×30cm	5Fr	30	Triple	D: 11	P: 3 M:3
	88	CVC-03 5F×13cm		13	Triple	D: 40	P: 7 M:7
	89	CVC-03 5.5F×8cm		8	Triple	D: 58	P: 10 M:11
	90	CVC-03 5.5F×13cm		13	Triple	D: 50	P: 8 M:8
	91	CVC-03 5.5F×15cm		15	Triple	D: 45	P: 7 M:7
	92	CVC-03 5.5F×16cm	5.5Fr	16	Triple	D: 42	P: 7 M:7
	93	CVC-03 5.5F×20cm		20	Triple	D: 37	P: 6 M:6
	94	CVC-03 7F×15cm		15	Triple	D: 67	P: 40 M:36
	95	CVC-03 7F×16cm		16	Triple	D: 65	P: 38 M:35
	96	CVC-03 7F×18cm		18	Triple	D: 60	P: 36 M:32
	97	CVC-03 7F×20cm	7Fr	20	Triple	D: 56	P: 31 M:28
	98	CVC-03 7F×30cm		30	Triple	D: 54	P:23 M:22
	99	CVC-03 8F×20cm		20	Triple	D: 105	P: 34 M:34
	100	CVC-03 8.5F×15cm		15	Triple	D: 130	P: 43 M:43
	101	CVC-03 8.5F×16cm	8.5Fr	16	Triple	D: 130	P: 42 M:42
	102	CVC-03 8.5F×20cm		20	Triple	D: 115	P: 36 M:36
	103	CVC-03 8.5F×30cm		30	Triple	D: 110	P:27 M:27
	104	CVC-03 11.5F×5cm		5	Triple	D: 105	P: 280 M:220
	105	CVC-03 11.5F×10cm		10	Triple	D: 95	P: 250 M:205
	106	CVC-03 11.5F×15cm	11.5Fr	15	Triple	D: 88	P: 210 M:190
	107	CVC-03 11.5F×20cm		20	Triple	D: 83	P:185 M:180
	108	CVC-03 11.5F×25cm		25	Triple	D: 70	P: 175 M:170
	109	CVC-03 11.5F×30cm		30	Triple	D: 60	P: 168 M:160
	110	CVC-03 12F×5cm	12Fr	5	Triple	D: 110	P: 290 M:230
	111	CVC-03 12F×10cm		10	Triple	D: 95	P: 250 M:210
	112	CVC-03 12F×15cm		15	Triple	D: 90	P: 210 M:190
	113	CVC-03 12F×20cm		20	Triple	D: 85	P:190 M:180
	114	CVC-03 12F×25cm		25	Triple	D: 75	P: 175 M:170
	115	CVC-03 12F×30cm	8.5Fr	30	Triple	D: 65	P: 170 M:165
	116	CVC-04 8.5F×15cm		15	Quad	D:60	P:35 M1:90 M2:35
	117	CVC-04 8.5F×20cm		20	Quad	D:58	P:30 M1:80 M2:30
	118	CVC-04 8.5F×30cm		30	Quad	D:46	P:23 M1:70 M2:22



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3 of 3