

EC DESIGN EXAMINATION CERTIFICATE

According to Annex II, Section 4 of the Directive 93/42/EEC on Medical Devices

Certificate Number

CE-MDD-0068/08/2019/DD.01

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 3th pages for details of product

Report Number : CE-MED-0068-01-DD

First Issue Date and Place : 22.08.2019 & İstanbul

Revision Number and Date : 00 / --

Validity Date : 06.02.2024

Issued by NOTICE, Notified Body 2764, this document approves that the design documentation of the mentioned product complies with Annex II, Section 4 of the 93/42/EEC Medical Devices Directive. The manufacturer is subject to EC surveillance in accordance with Annex II, Section 5 of 93/42/EEC Medical Devices Directive and unannounced audits.

Özlem Vicdan Akdağ
Chairman



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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	4Fr	30	Single	110
	33	CVC-01 4F×5cm		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	8Fr	30	Single	60
	45	CVC-01 8F×5cm		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	4Fr	25	Single	230
	50	CVC-01 8F×30cm		30	Single	215
	51	CVC-02 4F×5cm		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	7Fr	20	Double	D:13 P: 7
	60	CVC-02 7F×15cm		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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Product Name	No	Specification					
		Model Number	Size	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		30	Double	D:200	P: 195
	76	CVC-02 12F×5cm	12Fr	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		30	Triple	D: 11	P: 3 M:3
	88	CVC-03 5F×13cm	5Fr	13	Triple	D: 40	P: 7 M:7
	89	CVC-03 5.5F×8cm	5.5Fr	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		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	7Fr	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		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	8Fr	20	Triple	D: 105	P: 34 M:34
	100	CVC-03 8.5F×15cm	8.5Fr	15	Triple	D: 130	P: 43 M:43
	101	CVC-03 8.5F×16cm		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	11.5Fr	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		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	12Fr	30	Triple	D: 60	P: 168 M:160
	110	CVC-03 12F×5cm		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	8.5Fr	25	Triple	D: 75	P: 175 M:170
	115	CVC-03 12F×30cm		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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