

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-0017/02/2019/01

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) : - Guiding Catheter - Hydrophilic Coated Guide Wire
- PTCA Guide Wire - Angiographic Catheter
- Microcatheter - Balloon Dilatation Catheter
- Micro Guidewire - Peripheral Guidewire

Model(s) : Please see pages 2 – 10 for details of products

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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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Esentepe Mahallesi Milangaz Caddesi
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Product Name	Extension Wire	Core Wire Type	Specifications		
			Tip Coating Material	Tip Shape	Tip Stiffness
PTCA Guide Wire	--	Single	-Hydrophilic -Polymer Jacket & Hydrophilic -Hydrophilic with uncoating Tip -Without Coating	-Straight/shapable Tip - Angled Tip - Straight Tip	Floppy (0.7g) Super soft (0.9g) Moderate Soft(1g) Soft(2g) Standard(3g) Stiff(6g) Extra stiff(9g) Ultra Stiff(12g) Light Support Moderate Support - 0.8 g - 0.7 g - 1.0 g - 3.0 g - 9.0 g - 12.0 g - 20.0 g - 1.5 g - 2.7 g - 4.1 g - 0.6 g
	--	Composite	- Hydrophilic - Polymer Jacket & Hydrophilic	- Straight/shapable Tip - Pre-shape Tip - Angled Tip - 1mm Pre-shape Tip	- 0.8 g - 0.7 g - 0.3 g - 1.0 g - 0.6 g - 1.7 g - 3.5 g - 4.5 g
	150 cm 165 cm	--	--	--	--



Product Name	No	Model Number	Specification
Hydrophilic Coated Guide Wire	1	HGWS18045	45 cm - Straight tip - 0.018 inc
	2	HGWS18150	150 cm - Straight tip - 0.018 inc
	3	HGWS18180	180 cm - Straight tip - 0.018 inc
	4	HGWS18260	260 cm - Straight tip - 0.018 inc
	5	HGWS25150	150 cm - Straight tip - 0.025 inc
	6	HGWS25180	180 cm - Straight tip - 0.025 inc
	7	HGWS25260	260 cm - Straight tip - 0.025 inc
	8	HGWS32150	150 cm - Straight tip - 0.032 inc
	9	HGWS32180	180 cm - Straight tip - 0.032 inc
	10	HGWS32260	260 cm - Straight tip - 0.032 inc
	11	HGWS35150	150 cm - Straight tip - 0.035 inc
	12	HGWS35180	180 cm - Straight tip - 0.035 inc
	13	HGWS35260	260 cm - Straight tip - 0.035 inc
	14	HGWS38150	150 cm - Straight tip - 0.038 inc
	15	HGWS38180	180 cm - Straight tip - 0.038 inc
	16	HGWS38260	260 cm - Straight tip - 0.038 inc
	17	HGWA18150	150 cm - Angled tip - 0.018 inc
	18	HGWA18180	180 cm - Angled tip - 0.018 inc
	19	HGWA18260	260 cm - Angled tip - 0.018 inc
	20	HGWA25150	150 cm - Angled tip - 0.025 inc
	21	HGWA25180	180 cm - Angled tip - 0.025 inc
	22	HGWA25260	260 cm - Angled tip - 0.025 inc
	23	HGWA32150	150 cm - Angled tip - 0.032 inc
	24	HGWA32180	180 cm - Angled tip - 0.032 inc
	25	HGWA32260	260 cm - Angled tip - 0.032 inc
	26	HGWA35150	150 cm - Angled tip - 0.035 inc
	27	HGWA35180	180 cm - Angled tip - 0.035 inc
	28	HGWA35260	260 cm - Angled tip - 0.035 inc
	29	HGWA38150	150 cm - Angled tip - 0.038 inc
	30	HGWA38180	180 cm - Angled tip - 0.038 inc
	31	HGWA38260	260 cm - Angled tip - 0.038 inc
	32	HGWJ18150	150 cm - J tip - 0.018 inc
	33	HGWJ18180	180 cm - J tip - 0.018 inc
	34	HGWJ18260	260 cm - J tip - 0.018 inc
	35	HGWJ25150	150 cm - J tip - 0.025 inc
	36	HGWJ25180	180 cm - J tip - 0.025 inc
	37	HGWJ25260	260 cm - J tip - 0.025 inc
	38	HGWJ32150	150 cm - J tip - 0.032 inc
	39	HGWJ32180	180 cm - J tip - 0.032 inc
	40	HGWJ32260	260 cm - J tip - 0.032 inc
	41	HGWJ35150	150 cm - J tip - 0.035 inc
	42	HGWJ35180	180 cm - J tip - 0.035 inc
	43	HGWJ35260	260 cm - J tip - 0.035 inc
	44	HGWJ38150	150 cm - J tip - 0.038 inc
	45	HGWJ38180	180 cm - J tip - 0.038 inc
	46	HGWJ38045	45 cm - J tip - 0.038 inc
	47	HGWJ38260	260 cm - J tip - 0.038 inc



Product Name	No	Model Number	Specification
Balloon Dilatation Catheter - PTCA Balloon Dilatation Catheter	1	RX 1.5×9	1.5 mm×9 mm
	2	RX 1.5×10	1.5 mm×10 mm
	3	RX 1.5×12	1.5 mm×12 mm
	4	RX 1.5×15	1.5 mm×15 mm
	5	RX 1.5×18	1.5 mm×18 mm
	6	RX 1.5×20	1.5 mm×20 mm
	7	RX 1.5×25	1.5 mm×25 mm
	8	RX 1.5×30	1.5 mm×30 mm
	9	RX 1.75×9	1.75 mm×9 mm
	10	RX 1.75×10	1.75 mm×10 mm
	11	RX 1.75×12	1.75 mm×12 mm
	12	RX 1.75×15	1.75 mm×15 mm
	13	RX 1.75×18	1.75 mm×18 mm
	14	RX 1.75×20	1.75 mm×20 mm
	15	RX 1.75×25	1.75 mm×25 mm
	16	RX 1.75×30	1.75 mm×30 mm
	17	RX 2.0×9	2.0 mm×9 mm
	18	RX 2.0×10	2.0 mm×10 mm
	19	RX 2.0×12	2.0 mm×12 mm
	20	RX 2.0×15	2.0 mm×15 mm
	21	RX 2.0×18	2.0 mm×18 mm
	22	RX 2.0×20	2.0 mm×20 mm
	23	RX 2.0×25	2.0 mm×25 mm
	24	RX 2.0×30	2.0 mm×30 mm
	25	RX 2.25×9	2.25 mm×9 mm
	26	RX 2.25×10	2.25 mm×10 mm
	27	RX 2.25×12	2.25 mm×12 mm
	28	RX 2.25×15	2.25 mm×15 mm
	29	RX 2.25×18	2.25 mm×18 mm
	30	RX 2.25×20	2.25 mm×20 mm
	31	RX 2.25×25	2.25 mm×25 mm
	32	RX 2.25×30	2.25 mm×30 mm
	33	RX 2.5×9	2.5 mm×9 mm
	34	RX 2.5×10	2.5 mm×10 mm
	35	RX 2.5×12	2.5 mm×12 mm
	36	RX 2.5×15	2.5 mm×15 mm
	37	RX 2.5×18	2.5 mm×18 mm
	38	RX 2.5×20	2.5 mm×20 mm
	39	RX 2.5×25	2.5 mm×25 mm
	40	RX 2.5×30	2.5 mm×30 mm
	41	RX 2.75×9	2.75 mm×9 mm
	42	RX 2.75×10	2.75 mm×10 mm
	43	RX 2.75×12	2.75 mm×12 mm
	44	RX 2.75×15	2.75 mm×15 mm
	45	RX 2.75×18	2.75 mm×18 mm
	46	RX 2.75×20	2.75 mm×20 mm
	47	RX 2.75×25	2.75 mm×25 mm
	48	RX 2.75×30	2.75 mm×30 mm
	49	RX 3.0×9	3.0 mm×9 mm
	50	RX 3.0×10	3.0 mm×10 mm
	51	RX 3.0×12	3.0 mm×12 mm
	52	RX 3.0×15	3.0 mm×15 mm
	53	RX 3.0×18	3.0 mm×18 mm
	54	RX 3.0×20	3.0 mm×20 mm
	55	RX 3.0×25	3.0 mm×25 mm
	56	RX 3.0×30	3.0 mm×30 mm
	57	RX 3.25×9	3.25 mm×9 mm
	58	RX 3.25×10	3.25 mm×10 mm
	59	RX 3.25×12	3.25 mm×12 mm
	60	RX 3.25×15	3.25 mm×15 mm



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Product Name	No	Model Number	Specification
Balloon Dilatation Catheter - PTCA Balloon Dilatation Catheter	61	RX 3.25×18	3.25 mm×18 mm
	62	RX 3.25×20	3.25 mm×20 mm
	63	RX 3.25×25	3.25 mm×25 mm
	64	RX 3.25×30	3.25 mm×30 mm
	65	RX 3.5×9	3.5 mm×9 mm
	66	RX 3.5×10	3.5 mm×10 mm
	67	RX 3.5×12	3.5 mm×12 mm
	68	RX 3.5×15	3.5 mm×15 mm
	69	RX 3.5×18	3.5 mm×18 mm
	70	RX 3.5×20	3.5 mm×20 mm
	71	RX 3.5×25	3.5 mm×25 mm
	72	RX 3.5×30	3.5 mm×30 mm
	73	RX 4.0×9	4.0 mm×9 mm
	74	RX 4.0×10	4.0 mm×10 mm
	75	RX 4.0×12	4.0 mm×12 mm
	76	RX 4.0×15	4.0 mm×15 mm
	77	RX 4.0×18	4.0 mm×18 mm
	78	RX 4.0×20	4.0 mm×20mm
	79	RX 4.0×25	4.0 mm×25 mm
	80	RX 4.0×30	4.0 mm×30 mm

Product Name	No	Model Number	Specification
Balloon Dilatation Catheter - NC Coronary Dilatation Catheter	1	NCRX 1.5×6	1.5 mm×6 mm
	2	NCRX 1.5×8	1.5 mm×8 mm
	3	NCRX 1.5×9	1.5 mm×9 mm
	4	NCRX 1.5×10	1.5 mm×10 mm
	5	NCRX 1.5×12	1.5 mm×12 mm
	6	NCRX 1.5×15	1.5 mm×15 mm
	7	NCRX 1.5×18	1.5 mm×18 mm
	8	NCRX 1.5×20	1.5 mm×20 mm
	9	NCRX 1.5×25	1.5 mm×25 mm
	10	NCRX 1.5×30	1.5 mm×30 mm
	11	NCRX 2.0×6	2.0 mm×6 mm
	12	NCRX 2.0×8	2.0 mm×8 mm
	13	NCRX 2.0×9	2.0 mm×9 mm
	14	NCRX 2.0×10	2.0 mm×10 mm
	15	NCRX 2.0×12	2.0 mm×12 mm
	16	NCRX 2.0×15	2.0 mm×15 mm
	17	NCRX 2.0×18	2.0 mm×18 mm
	18	NCRX 2.0×20	2.0 mm×20 mm
	19	NCRX 2.0×25	2.0 mm×25 mm
	20	NCRX 2.0×30	2.0 mm×30 mm
	21	NCRX 2.25×6	2.25 mm×6 mm
	22	NCRX 2.25×8	2.25 mm×8 mm
	23	NCRX 2.25×9	2.25 mm×9 mm
	24	NCRX 2.25×10	2.25 mm×10 mm
	25	NCRX 2.25×12	2.25 mm×12 mm
	26	NCRX 2.25×15	2.25 mm×15 mm
	27	NCRX 2.25×18	2.25 mm×18 mm
	28	NCRX 2.25×20	2.25 mm×20 mm
	29	NCRX 2.25×25	2.25 mm×25 mm
	30	NCRX 2.25×30	2.25 mm×30 mm
	31	NCRX 2.5×6	2.5 mm×6 mm
	32	NCRX 2.5×8	2.5 mm×8 mm
	33	NCRX 2.5×9	2.5 mm×9 mm
	34	NCRX 2.5×10	2.5 mm×10 mm
	35	NCRX 2.5×12	2.5 mm×12 mm
	36	NCRX 2.5×15	2.5 mm×15 mm
	37	NCRX 2.5×18	2.5 mm×18 mm



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Product Name	No	Model Number	Specification
Balloon Dilatation Catheter	38	NCRX 2.5×20	2.5 mm×20 mm
	39	NCRX 2.5×25	2.5 mm×25 mm
	40	NCRX 2.5×30	2.5 mm×30 mm
	41	NCRX 2.75×6	2.75 mm×6 mm
	42	NCRX 2.75×8	2.75 mm×8 mm
	43	NCRX 2.75×9	2.75 mm×9 mm
	44	NCRX 2.75×10	2.75 mm×10 mm
	45	NCRX 2.75×12	2.75 mm×12 mm
	46	NCRX 2.75×15	2.75 mm×15 mm
	47	NCRX 2.75×18	2.75 mm×18 mm
	48	NCRX 2.75×20	2.75 mm×20 mm
	49	NCRX 2.75×25	2.75 mm×25 mm
	50	NCRX 2.75×30	2.75 mm×30 mm
	51	NCRX 3.0×6	3.0 mm×6 mm
	52	NCRX 3.0×8	3.0 mm×8 mm
	53	NCRX 3.0×9	3.0 mm×9 mm
	54	NCRX 3.0×10	3.0 mm×10 mm
	55	NCRX 3.0×12	3.0 mm×12 mm
	56	NCRX 3.0×15	3.0 mm×15 mm
	57	NCRX 3.0×18	3.0 mm×18 mm
	58	NCRX 3.0×20	3.0 mm×20 mm
	59	NCRX 3.0×25	3.0 mm×25 mm
	60	NCRX 3.0×30	3.0 mm×30 mm
	61	NCRX 3.25×6	3.25 mm×6 mm
	62	NCRX 3.25×8	3.25 mm×8 mm
	63	NCRX 3.25×9	3.25 mm×9 mm
	64	NCRX 3.25×10	3.25 mm×10 mm
	65	NCRX 3.25×12	3.25 mm×12 mm
	66	NCRX 3.25×15	3.25 mm×15 mm
	67	NCRX 3.25×18	3.25 mm×18 mm
	68	NCRX 3.25×20	3.25 mm×20 mm
	69	NCRX 3.25×25	3.25 mm×25 mm
	70	NCRX 3.25×30	3.25 mm×30 mm
- NC Coronary Dilatation Catheter	71	NCRX 3.5×6	3.5 mm×6 mm
	72	NCRX 3.5×8	3.5 mm×8 mm
	73	NCRX 3.5×9	3.5 mm×9 mm
	74	NCRX 3.5×10	3.5 mm×10 mm
	75	NCRX 3.5×12	3.5 mm×12 mm
	76	NCRX 3.5×15	3.5 mm×15 mm
	77	NCRX 3.5×18	3.5 mm×18 mm
	78	NCRX 3.5×20	3.5 mm×20 mm
	79	NCRX 3.5×25	3.5 mm×25 mm
	80	NCRX 3.5×30	3.5 mm×30 mm
	81	NCRX 3.75×6	3.75 mm×6 mm
	82	NCRX 3.75×8	3.75 mm×8 mm
	83	NCRX 3.75×9	3.75 mm×9 mm
	84	NCRX 3.75×10	3.75 mm×10 mm
	85	NCRX 3.75×12	3.75 mm×12 mm
	86	NCRX 3.75×15	3.75 mm×15 mm
	87	NCRX 3.75×18	3.75 mm×18 mm
	88	NCRX 3.75×20	3.75 mm×20 mm
	89	NCRX 3.75×25	3.75 mm×25 mm
	90	NCRX 3.75×30	3.75 mm×30 mm
	91	NCRX 4.0×6	4.0 mm×6 mm
	92	NCRX 4.0×8	4.0 mm×8 mm
	93	NCRX 4.0×9	4.0 mm×9 mm
	94	NCRX 4.0×10	4.0 mm×10 mm
	95	NCRX 4.0×12	4.0 mm×12 mm
	96	NCRX 4.0×15	4.0 mm×15 mm
	97	NCRX 4.0×18	4.0 mm×18 mm



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Product Name	No	Model Number	Specification
Balloon Dilatation Catheter - NC Coronary Dilatation Catheter	98	NCRX 4.0×20	4.0 mm×20mm
	99	NCRX 4.0×25	4.0 mm×25 mm
	100	NCRX 4.0×30	4.0 mm×30 mm
	101	NCRX 4.5×6	4.5 mm×6 mm
	102	NCRX 4.5×8	4.5 mm×8 mm
	103	NCRX 4.5×9	4.5 mm×9 mm
	104	NCRX 4.5×10	4.5 mm×10 mm
	105	NCRX 4.5×12	4.5 mm×12 mm
	106	NCRX 4.5×15	4.5 mm×15 mm
	107	NCRX 4.5×18	4.5 mm×18 mm
	108	NCRX 4.5×20	4.5 mm×20mm
	109	NCRX 5.0×6	5.0 mm×6mm
	110	NCRX 5.0×8	5.0 mm×8mm
	111	NCRX 5.0×9	5.0 mm×9mm
	112	NCRX 5.0×10	5.0 mm×10mm
	113	NCRX 5.0×12	5.0 mm×12mm
	114	NCRX 5.0×15	5.0 mm×15mm
	115	NCRX 5.0×18	5.0 mm×18mm
	116	NCRX 5.0×20	5.0 mm×20mm

Product Name	Core Wire Type	Specifications		
		Wire Coating Material	Tip Stiffnees	Tip Shape
Peripheral Guidewire	Single	- Polymer Jacket & Hydrophilic - Hydrophilic	1g - 3g - 4g - 6g - 8g 12g - 20g - 30g - 40g	- Straight Tip - Angled Tip
	Composite	- Polymer Jacket & Hydrophilic - Hydrophilic	3g - 4g - 7.5g - 12g	- Straight Tip - Pre-shaped Tip



Product Name	Number of Side Holes	Catheter Other Diameter(Fr)	Tip Configuration of Models
Guiding Catheter	Zero Side Hole	5.0 – 6.0 – 7.0 – 8.0 – 9.0 – 10.0	-JL3.5 – JL4.0 – JL4.5 – JL5.0 – AL0.75 – AL1.0 – AL2.0 – AR1.0 AR2.0 – XB4.0 – JL3.0 – JL3.5 LT – JL3.5 ST – JL4.0 LT – JL4.0 ST – JL5.0 LT – JL6.0 – JCL3.5 – JCL4.0 – XB2.5 – XB3.0 – XB3.0 LT – XB3.5 – XB3.5 LT – XB4.0 LT – XBC3.0 – XBC3.5 – XBC3.5 LT – XBC4.0 – XBC4.5 – XBLAD3.0 – XBLAD3.5 – XBLAD3.5 LT – XBLAD4.0 – XBLAD4.5 – AL1.0 LT – AL1.0 ST – AL1.5 – AL2.0 LT – AL2.0 ST – AL3.0 – AL3.0 LT – JR3.5 – JR3.5 LT – JR4.0 – JR4.0 LT – JR4.0 ST – JR4.5 ST – JR5.0 – JR5.0 LT – XBR1.0 – XBRCA – 3DRC – 3DRC LT – AR1.0 LT – AR2.0 LT – RBL4 – RBL4.5 – RBL5 – CAS2 – CAS3 – SON1 – BL(Tilon) – RB – Barbeau – 3D LIMA 90 – IM Barbeau – JFL – JFR – MPA1 LT – MPA1 – MPA2 – MPB1 – H-STICK – H-STICK LT – LCB – LCB LT – RCB – IM – IM LT – JL2.0 LT – JR1.0 – JR2.0 – JR3.5 ST – JR6.0 – AL R1.2 – AL0.75 ST – AL1.5 ST – AL3.0 ST – AR3.0 – XB2.0 – XB2.75 – XB3.25 – XB4.5 – XBC2.5 – XBC2.75 – XBC3.25 – XBC3.75 – XBR2.0 – JCL4.5 – JCL5.0 – JCR3.5 – JCR4.0 – JCV – JFL LT – JFL ST – DA75 – DA90 – Barbeau LT CBL – Contra1 – Contra2 – EBU2.0 – EBU3.0 – EBU3.25 – EBU3.5 – EBU3.75 EBU4.0 – EBU4.5 – EBU5.0 – EGB – H1 – MPC – MPD – NR4.0 – RB LT – RCV – RCV1 – RDC – RRAD5.0 – RRAD6.0 – RRAD6.0 XB – SCR3.5 – SCR4.0 – SCR5.0 – STR – VER – CAS1 – SON2 – JL4.5 LT – XB3.75 – JFR LT – JL4.5 ST – JL5.0 ST – JR 4.5 – JFR ST
	Two Side Hole	5.0 - 6.0 - 7.0 - 8.0 - 9.0 - 10.0	- JL3.0 – JL3.5 – JL4.0 ST – JL4.0 – JL5.0 – JCL3.5 – XB3.0 – XB3.5 – XB4.0 – XBC3.0 – XBC3.5 – XBLAD3.0 – XBLAD3.5 – XBLAD4.0 – AL0.75 – AL1.0 ST – AL1.0 – AL1.5 – AL2.0 – AL3.0 – JR3.5 – JR4.0 – JR5.0 – XBR1.0 – XBRCA – 3DRC – AR1.0 – AR2.0 – MPA1 MPB1 – H-STICK – LCB – RCB – IM – JL3.5 ST – JL5.0 ST – JR1.0 – JR2.0 – JR3.5 ST – JR4.5 ST – JR4.0 ST – JR6.0 – AL R1.2 – AL1.5 ST – AL2.0 ST – XB4.5 – XBC4.0 – XBC4.5 – XBLAD4.5 – XBR2.0 – JCL4.0 – JCL4.5 – JCR3.5 – JCR4.0 – NR4.0 – SCR3.5 – SCR4.0 – JL4.5



Product Name	Number of Side Holes	Catheter Other Diameter(Fr)	Tip Configuration of Models
Angiographic Catheter	Zero Side Hole	4.0 - 5.0 - 6.0	JL3.5 / JL4.5 / JL4.0 / JL5.0 / JR3.5 / JR4.0 / JR5.0 / AL1 / AL2 / AL3 / C1 / C2 / C3 / CHG2.5 / CHG-B / CHG-C / DAV / FC3 / H1 / H2 / H3 / HN5 / JB1 / JB2 / KMP / LEV1 / MIK / MPA1 / MPA2 / MPA3 / MPA / MPB / RBT / RC1 / RC2 / RDC / RH / RIM / RLG / RS / SHK1.0 / SIM1 / SIM2 / SIM3 / TEGT / VANSCHIE1 / VANSCHIE2 / VANSCHIE3 / VANSCHIE4 / VANSCHIE5 / VERT / VS / VS1 / VS2 / VS3 / VTK / WNBG / YASHIRO / AR-JP / AR-R5 / AR-RC / BP-JL / BP-JR / IM / IM-JP type / IM-Round tip / IM-Short tip / JL2.5 / JL6.0 / JR4.5 / MP3.5 / MP4.0 / STR / TIG II- 3.5 / XB3.5 / AR 1.0 / AR 2.0 / TIG I- 4.5 / TIG I- 5.0 / JL1.5 / JL2.0 / JR1.5 / JR2.0 / JR2.5 / JR3.0 / JR6.0 / JCL3.5 / JCL4.0 / AL0.75 / AL1.5 / AL4 / AR MOD / AR1 MOD / AR2 MOD / MPB1 / SRC / 3DRC / SON2 / SON3 / CAS1 / CAS2 / CAS3 / EGB 1 / RB / RBL4.0 / RBL4.5 / RBL5.0 / RBMP / RCB / LCB / 3D LIMA / PIG(S) / SIM4 / H5 / H6 / NT1 / NT2 / NT3 / NT4 / NT5 / BS1 / BS2 / BS3 / BER / Hockey Stick / MANI / OS 1 / OS 2 / J-Curve 0.6 / J-Curve 1.1 / J-Curve 1.4 / RUC / TIG II- 4.0 / TIG II- 4.5 / TIG II- 5.0 / AR 3.0 / JL3.0
	One Side Hole	4.0 - 5.0 - 6.0	BLK / TIG II- 3.5 / TIG II- 4.0 / TIG I-3.5 / TIG I-4.0 / TIG I-5.0 / RBMP
	Two Side Hole	4.0 - 5.0 - 6.0	MPA1 / MPA2 / MPA3 / JL4.0 / JR3.5 / MP2.5 / MP3.0 / MP3.5 / MP4.0 / JR4.0 / MPB2 / Barbeau / SON1 / SON2 / CAS2 / RBL4.0 / RBL5.0 / RBMP / PIG(S) / C1 / C2 / C3 / RDC / HK0.8 / HK1.0 / SHK 0.8 / SHK 1.0 / MPA / RIM
	Three Side Hole	4.0	JL4.0 / JR4.0
	Four Side Hole	4.0 - 5.0 - 6.0	SON1 / SON1.5 / SON3 / CAS1 / CAS2 / PIG(S)
	Six Side Hole	4.0 - 5.0 - 6.0	PIG(S) / PIG145° / PIG155° / STR
	Eight Side Hole	4.0 - 5.0 - 6.0	PIG(S) / STR
	Ten Side Hole	5.0	PIG / PIG(S)
	Twelve Side Hole	6.0	AL1 / AL2



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Product Name	Tip shape
Microcatheter - {MCS series (stainless steel) }	- Straight Tip
	- Angled Tip
	- 45° Angle Tip
	- 90° Angle Tip
	- J Tip
Microcatheter - { MCT Series (Tungsten)}	- Straight Tip
	- Angled Tip
Microcatheter - { MCK Series }	- Straight Tip

Product Name	Tip shape
Micro Guidewire - (MGW series)	- Straight Tip
	- 45° Angle Tip
	- 60° Angle Tip
Micro Guidewire - (MGWN series)	- Straight - Soft Tip
	- Straight-Support Tip
	- Note:There is not tip shape for MGWN115-14E of model.
	- Straight-Soft Tip
Micro Guidewire - (MGWNA Series)	- Pre-shaped - Soft Tip
	- Straight -Standard Tip
	- Pre-shaped-Standard Tip
	- Straight-Distal Segment 35cm Tip
Micro Guidewire - (MGWNB Series)	- Straight-Distal Segment 45cm Tip
	- Straight-Support-Distal Segment 35cm Tip
	- Straight Tip
Micro Guidewire - (MGWNC Series)	- Straight Tip
	- Straight-Standard Tip
	- Straight-Soft Tip
	- Straight -Floppy Tip
	- Straight-Platinum Tip
	- Straight-Extra Support Tip



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www.notice.com.tr

EC Certificate
Directive 93/42/EEC Annex II, excluding Section 4
Full Quality Assurance System
Medical Devices

Registration No.: HD 60147577 0001

Report No.: 17054840 009

Manufacturer: Shunmei Medical
Co., Ltd.
R401 of building B, No.8 of
1st Jinglong Road, Baolong
Industrial Zone, LongGang District,
518116 Shenzhen, Guangdong
P.R. China

Products: Medical Devices

(see attachment for products and additional site included)

Replaces Approval, Registration No.: HD 60136963 0001

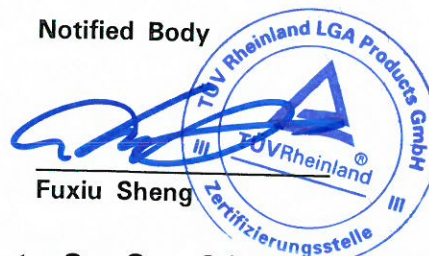
Expiry Date: 2024-05-26

The Notified Body hereby declares that the requirements of Annex II, excluding section 4 of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex II, section 5 of the aforementioned directive. For placing on the market of class III devices covered by this certificate an EC design-examination certificate according to Annex II, section 4 is required.

Effective Date: 2020-08-09

Date: 2020-08-09

Notified Body



TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC
concerning medical devices with the identification number 0197.

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Doc. 1/2 Rev. 0

**Attachment to
Certificate**

Registration No.: HD 60147577 0001
Report No.: 17054840 009

Manufacturer: Shunmei Medical
Co., Ltd.
R401 of building B, No.8 of
1st Jinglong Road, Baolong
Industrial Zone, LongGang District,
518116 Shenzhen, Guangdong
P.R. China

Products:

- Disposable Pressure Transducers
- Hemodialysis Catheter Kits
- Connecting Tubings
- Introducer Sets
- Guide Wires
- Hemostasis Valve Sets
- Ureteral Stent Sets
- Introducer Needles
- Angiographic Syringes
- Closed Suction Kits
- Drainage Catheters
- Tracheostomy Tubes
- Percutaneous Nephrostomy Sets
- Cervical Ripening Balloons
- Postpartum Balloons with Rapid Instillation Components

Date: 2020-08-09

Notified Body


Fuxiu Sheng



TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Doc. 2/2, Rev.0

**Attachment to
Certificate**

Registration No.: HD 60147577 0001
Report No.: 17054840 009

Manufacturer: Shunmei Medical
Co., Ltd.
R401 of building B, No.8 of
1st Jinglong Road, Baolong
Industrial Zone, LongGang District,
518116 Shenzhen, Guangdong
P.R. China

Aspects of manufacture concerned with securing and
maintaining sterile conditions:

- Stopcocks
- Manifolds
- Balloon Inflation Devices
- Dose Control Syringes
- Manifold Kits
- Angio-closure Pads
- TR-Closure Bands
- Needle-free Connectors

Site included:

Huizhou branch of Shunmei Medical Co., Ltd
Yifa industrial zone, Dushi village, Pingtan town,
HuiYang District, HuiZhou City, China

Date: 2020-08-09

Notified Body



Fuxiu Sheng



Certificate

Quality Management System
EN ISO 13485:2016

Registration No.: SX 2027603-1

Organization: Shunmei Medical Co., Ltd.
R401 of building B,
No.8 of 1st Jinlong Road,
Baolong Industrial Zone, LongGang District
Shenzhen
518116 Guangdong
P.R. China

Scope: Design and Development, Manufacture and Distribution of Disposable
Pressure Transducers, Hemodialysis Catheter Kits, Connecting Tubings,
Introducer Sets, Guide Wires, Hemostasis Valve Sets, Introducer Needles,
Angiographic Syringes, Stopcocks, Manifolds, Balloon Inflation Devices,
Dose Control syringes, Manifold kits, TR-Closure Bands


TÜVRheinland

The Certification Body of TÜV Rheinland LGA Products GmbH certifies that the organization has established and applies a quality management system for medical devices.
Proof has been furnished that the requirements specified in the abovementioned standard are fulfilled. The quality management system is subject to yearly surveillance.

Report No.: 10920630-100
Effective date: 2022-06-16
Expiry date: 2025-02-27
Issue date: 2022-06-16



Dipl.-Ing. W. Hsu
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

Certificate

Quality Management System
EN ISO 13485:2016

Registration No.: SX 2027603-1

Organization: Shunmei Medical Co., Ltd.
R401 of building B,
No.8 of 1st Jinlong Road,
Baolong Industrial Zone, LongGang District
Shenzhen
518116 Guangdong
P.R. China

The scope of certification also covers the following:

No.	Facility	Scope
/01	c/o Shunmei Medical Co., Ltd. R401 of building B, No.8 of 1st Jinlong Road, Baolong Industrial Zone, LongGang District Shenzhen 518116 Guangdong P.R. China	Manufacture of Disposable Pressure Transducers, Connecting Tubings, Stopcocks, Manifolds, Balloon Inflation Devices, Dose Control syringes, Hemostasis Valve Sets, TR-Closure Bands
/02	c/o Shunmei Medical Co., Ltd Huizhou branch Yifa 3rd road, Yifa Industrial Zone, Pingtan Town, Huiyang District, Huizhou, 516259, Guangdong, P.R. China	Design and Development, Manufacture and Distribution of Disposable Pressure Transducers, Hemodialysis Catheter Kits, Connecting Tubings, Introducer Sets, Guide Wires, Hemostasis Valve Sets, Introducer Needles, Angiographic Syringes, Stopcocks, Manifolds, Balloon Inflation Devices, Dose Control Syringes, Manifold Kits, TR-Closure Bands

Report No.: 10920630-100
Effective date: 2022-06-16
Expiry date: 2025-02-27
Issue date: 2022-06-16


Dipl.-Ing. W. Hsu
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

Certificate



Quality Management System
EN ISO 13485:2016

Registration No.: SX 2027603-1

Organization: Shunmei Medical Co., Ltd.
R401 of building B,
No.8 of 1st Jinlong Road,
Baolong Industrial Zone, LongGang District
Shenzhen
518116 Guangdong
P.R. China

The scope of certification also covers the following:

/03	c/o Hunan Xinke Medical Co., Ltd. 3rd and 4th Floor, Building 7, Phase II, Innovation and Pioneer Park, Tianyue New District, Pingjiang County, Yueyang, 414513 Hunan P.R. China	Manufacture of Disposable Pressure Transducers, Hemodialysis Catheter Kits, Connecting Tubings, Introducer Sets, Guide Wires, Hemostasis Valve Sets, Introducer Needles, Angiographic Syringes, Stopcocks, Manifolds, Balloon Inflation Devices, Dose Control Syringes, Manifold Kits, TR-Closure Bands
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TÜVRheinland

Report No.: 10920630-100
Effective date: 2022-06-16
Expiry date: 2025-02-27
Issue date: 2022-06-16



A handwritten signature in blue ink, likely belonging to Dipl.-Ing. W. Hsu.

Dipl.-Ing. W. Hsu
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany



NOTICE BELGELENDİRME MUAYENE ve DENETİM HİZMETLERİ A.Ş.

Hereby certifies that

Shunmei Medical Co., Ltd

With the address(es) below:

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
Factory: 3rd and 4th Floor, Building 7, Phase II, Innovation and Pioneer Park, Tianyue New District, Pingjiang Country, Yueyang City, Hunan Province

has implemented a quality management system according to

EN ISO 13485:2016

The scope of this Quality Management System includes:

Design & development, manufacturing and sales of medical devices: Guiding Catheter, Hydrophilic Coated Guide Wire, PTCA Guide Wire, Balloon Dilatation Catheter, Angiographic Catheter, Central Venous Catheter Kit, Introducer Sets, Hemodialysis Catheter kits, Hemostasis Valve Set, Guidewires, Introducer Needle, Disposable Pressure Transducers, Connecting Tubing, Angiographic Syringes, Drainage Catheter Kit, Cervical Ripening Balloon, Ureteral Stent Set, Percutaneous Nephrostomy Sets, Postpartum Balloon with Rapid Instillation Components, Dose Control Syringe, Stopcocks, Needle-free Connector, Manifold Kit, Manifolds, Balloon Inflation Devices, TR-closure Band, Microcatheter, Micro Guidewire, Peripheral Guidewire

Certificate Number : ISO.MED.0017.02.2019.RC
Issue Date : 2019.02.11
Reissue Date : 2022.02.15
Validity Date : 2025.02.14
Revision : --
Revision Date : --

Approved by
Özlem VİCDAN AKDAĞ
Chairman of the Board

Signature

According to ISO/IEC 17021 rules, the company is subject to surveillance audits. This certificate is valid as long as the company complies with NOTICE certification rules. You can check the validity of this certificate through contacting the phone number and email address given below. The validity can also be verified via Certificate Query part in our website: www.notice.com.tr

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Esentepe Mahallesi Milangaz Caddesi No:75/A/92 Kartal / İstanbul / TÜRKİYE
Tel: 00 90 216 504 16 98 – e-posta: info@notice.com.tr



Supplementary Information to ISO.MED.0017.02.2019.RC

Audited Addresses

Headquarters	: R401 of building B, No.8 of 1st Jinlong Road, Baolong Industrial Zone, Longgang District, Shenzhen 518116, Guangdong, China
	: R401 of building B, No.8 of 1st Jinlong Road, Baolong Industrial Zone, Longgang District, Shenzhen 518116, Guangdong, China
Production	: Yifa 3rd road, Yifa Industrial Zone, Pingtan Town, Huiyang District, Huizhou, Guangdong, China
	: 3rd and 4th Floor, Building 7, Phase II, Innovation and Pioneer Park, Tianyue New District, Pingjiang Country, Yueyang City, Hunan Province
Sterilization	: Yifa 3rd road, Yifa Industrial Zone, Pingtan Town, Huiyang District, Huizhou, Guangdong, China

Issue Date : 2019.02.11
Reissue Date : 2022.02.15
Validity Date : 2025.02.14
Revision : --
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