
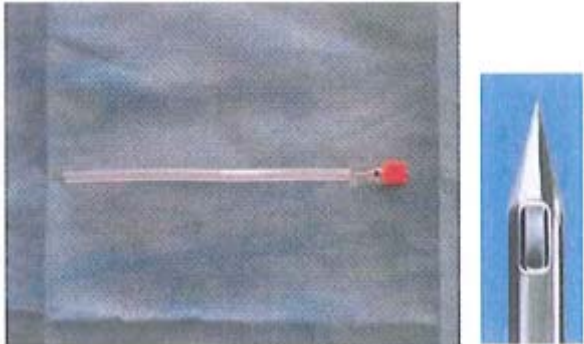


Product: Spinal Needle

Zhejiang Runqiang Medical Instruments Co., Ltd

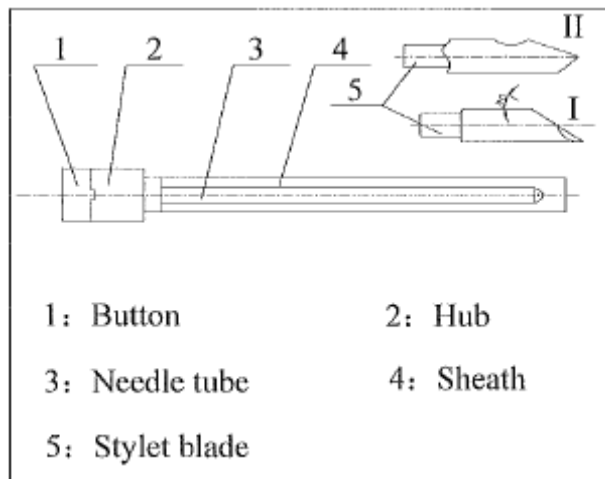
Parameter	Method	Specification
Product Description	-	<p>The product spinal needle is made up of three parts:</p> <ul style="list-style-type: none"> - Spinal needle (needle tube + needle hub) - Stylet (stylet blade + button) - Sheath <p>There are two different types of spinal needles available: Spinal Needle Type I: Quincke needle (AN-SI)</p>  <p>[Source: Design dossier of anaesthesia needle and anaesthesia kit CE/AS-01-01 Zhejiang Runqiang Medical Co., Ltd.)</p> <p>Spinal Needle Type II: Pencil point needle (AN-SII)</p>  <p>[Source: Design dossier of anaesthesia needle and anaesthesia kit CE/AS-01-01 Zhejiang Runqiang Medical Co., Ltd.)</p>
Intended Use	MDD 93/42/EEC	For regional anaesthesia involving injection of local anaesthetic into subarachnoid space (subarachnoid block) in clinics.
Risk Class	MDD 93/42/EEC	Class III, rule 6
UMDNS-Code	-	12753
Manufacturing date	-	YYYY/MM
Expiry Date	-	YYYY/MM
Sterility	EN ISO 11135-1 EN ISO 11737-1 EN ISO 11737-2	Sterile by EO Gas
Shelf Life	EN ISO 11607-1 EN ISO 11607-2	2 years
Cytotoxicity	ISO 10993-5	Product + packaging: Viability \geq 70 %
Sensitization	ISO 10993-10	Product + packaging: No visible change
Irritation or intracutaneous reactivity	ISO 10993-10	Product + packaging: No erythema, no oedema
Acute Systemic Toxicity	ISO 10993-11	Product: Normal, no symptoms
Bacterial Endotoxins	GB/T14233.1	< 2.15 EU/product
EO-Residuals	ISO 10993-7	< 0.1 mg
Limits for acidity and alkalinity	ISO 9626 Annex A	\geq 0.04 ml Sodium Hydroxide or \geq 0.12 ml Hydrochloric Acid

Product: Spinal Needle

Zhejiang Runqiang Medical Instruments Co., Ltd

Parameter	Method	Specification
Shelf Life	ISO 11607 ISO 11737-2	2 years
Batch numbers	-	<ul style="list-style-type: none"> Printed as variable data on primary, secondary and tertiary packing 4 figures YYYY taken from purchase confirmation 'XXX/0YYYY' adding 2 figures AA as running no. starting with 01 batch no.: YYYYAA
Generation of Analytical Certificates	-	Where definite figures are applicable statements like "complies" are not acceptable.
Storage Conditions	ISO 11607	<ol style="list-style-type: none"> Not allowed to pressed under heavy load No direct sun To be stored dry (away from rain and snow) Soft handling during transportation Stored in cool, dry (humidity < 80%), well-ventilated and clean place Stored free of caustic gases

Components:



[Source: Design dossier of anaesthesia needle and anaesthesia kit CE/AS-01-01 Zhejiang Runqiang Medical Co., Ltd.)

Materials	-	Needle tube & stylet blade: 304 stainless steel Hub: K-resin Button: ABS Sheat: PP																																				
L1 Effective needle length in mm L2 Overall needle length in mm L3 Sheath length in mm (Definition of L1, L2, L3 see Appendix II: Technical Drawings)	YY0321.2-2010	For Spinal Needle Type I: <table border="1"> <thead> <tr> <th>L1 (+/- 1mm)</th> <th>L2 (+/- 1mm)</th> <th>L3 (+ 8/- 2mm)</th> </tr> </thead> <tbody> <tr><td>38</td><td>53</td><td>100</td></tr> <tr><td>58</td><td>73</td><td>100</td></tr> <tr><td>75</td><td>90</td><td>100</td></tr> <tr><td>88</td><td>103</td><td>100</td></tr> <tr><td>100</td><td>115</td><td>130</td></tr> <tr><td>110</td><td>125</td><td>130</td></tr> <tr><td>120</td><td>135</td><td>130</td></tr> </tbody> </table> For Spinal Needle Type II: <table border="1"> <thead> <tr> <th>L1 (+/- 1mm)</th> <th>L2 (+ 0.3/- 0.5mm)</th> <th>L3 (+ 8/- 2mm)</th> </tr> </thead> <tbody> <tr><td>75</td><td>89.5</td><td>100</td></tr> <tr><td>88</td><td>102.5</td><td>100</td></tr> <tr><td>100</td><td>114.5</td><td>130</td></tr> </tbody> </table>	L1 (+/- 1mm)	L2 (+/- 1mm)	L3 (+ 8/- 2mm)	38	53	100	58	73	100	75	90	100	88	103	100	100	115	130	110	125	130	120	135	130	L1 (+/- 1mm)	L2 (+ 0.3/- 0.5mm)	L3 (+ 8/- 2mm)	75	89.5	100	88	102.5	100	100	114.5	130
L1 (+/- 1mm)	L2 (+/- 1mm)	L3 (+ 8/- 2mm)																																				
38	53	100																																				
58	73	100																																				
75	90	100																																				
88	103	100																																				
100	115	130																																				
110	125	130																																				
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L1 (+/- 1mm)	L2 (+ 0.3/- 0.5mm)	L3 (+ 8/- 2mm)																																				
75	89.5	100																																				
88	102.5	100																																				
100	114.5	130																																				

Product: Spinal Needle

Zhejiang Runqiang Medical Instruments Co., Ltd

Parameter	Method	Specification				
		120	134.5	130		
Outer diameter needle tube in G/ mm	ISO 9626:1991 In mm to the nearest 0.05mm for O.D. < 0.6mm In mm to the nearest 0.1mm for O.D. ≥ 0.6mm	Spinal Needle Type I				
		OD in G	OD in mm	OD Tolerances in mm		
		27	0.4	0.400-0.420		
		26	0.45	0.440-0.470		
		25	0.5	0.500-0.530		
		24	0.55	0.550-0.580		
		23	0.6	0.600-0.673		
		22	0.7	0.698-0.730		
		21	0.8	0.800-0.830		
		20	0.9	0.860-0.920		
		19	1.1	1.030-1.100		
		18	1.2	1.200-1.300		
		17	1.4	1.400-1.510		
		16	1.6	1.600-1.690		
		15	1.8	1.750-1.900		
		Spinal Needle Type II				
		OD in G	OD in mm	OD Tolerances in mm		
		27	0.4	0.400-0.420		
		26	0.45	0.440-0.470		
		25	0.5	0.500-0.530		
		24	0.55	0.550-0.580		
		23	0.6	0.600-0.673		
		22	0.7	0.698-0.730		
		21	0.8	0.800-0.830		
		20	0.9	0.860-0.920		
		Inner diameter needle tube in mm	ISO 9626:1991	Spinal Needle Type I		
OD [G]	OD [mm]			ID [mm]	IDmin [mm]	Specification
27	0.4			0.295	0.241	Thin-walled
26	0.45			0.335	0.292	Thin-walled
25	0.5			0.395	0.292	Thin-walled
24	0.55			0.43	0.343	Thin-walled
23	0.6			0.52	0.360	Thin-walled
22	0.7			0.57	0.440	Thin-walled
21	0.8			0.67	0.530	Thin-walled
20	0.9			0.76	0.610	Thin-walled
19	1.1			0.91	0.750	Thin-walled
18	1.2			1.11	0.910	Thin-walled
17	1.4			1.3	1.156	Thin-walled
16	1.6			1.48	1.283	Thin-walled
15	1.8			1.64	1.460	Thin-walled
Spinal Needle Type II						
OD [G]	OD [mm]			ID [mm]	IDmin [mm]	Specification
27	0.4			0.295	0.241	Thin-walled
26	0.45			0.335	0.292	Thin-walled
25	0.5			0.395	0.292	Thin-walled
24	0.55			0.43	0.343	Thin-walled
23	0.6			0.52	0.360	Thin-walled

Product: Spinal Needle

Zhejiang Runqiang Medical Instruments Co., Ltd

Parameter	Method	Specification				
				21	0.8	0.67
		20	0.9	0.76	0.610	Thin-walled
Needle tube	BS 6169-1989/ ISO 9626:1991	<ul style="list-style-type: none"> - Tubing made from austenitic stainless steel in accord. with ISO9626:1991 - straight - regular cross section - regular wall thickness - free from defects - smooth - no impurities - should be parallel: Deviation max. +/- 15° 				
Needle point	BS 6169-1989	<ul style="list-style-type: none"> - no cutting edges around inner aspect of the bevel (only applicable for Spinal Needle Type I) - tip should be burr free, no flat head and no hook 				
Needle deflection/ stiffness	ISO 9626:1991 Annex C	Designated metric size in mm	Span in mm +/- 0.1	Bending force in N +/- 0.1	Max. deflection in mm	
		0.4	7.5	5.5	0.65	
		0.45	10	5.5	0.61	
		0.5	10	7	0.43	
		0.55	10	10	0.55	
		0.6	12.5	10	0.45	
		0.7	15	10	0.50	
		0.8	15	15	0.50	
		0.9	17.5	15	0.65	
		1.1	25	10	0.55	
		1.2	25	20	0.55	
		1.4	25	22	0.55	
		1.6	25	22	0.30	
1.8	25	25	0.45			
Needle toughness/ resistance to breakage	ISO 9626:1991 Annex D	Designated metric size in mm	Distance between rigid support and point of application of bending force in mm +/- 0.1	Bending Angle		
		0.4	8	20°		
		0.45	10	20°		
		0.5	10	20°		
		0.55	12.5	20°		
		0.6	15	20°		
		0.7	17.5	20°		
		0.8	20	20°		
		0.9	25	20°		
		1.1	27.5	20°		
		1.2	30	20°		
		1.4	31.5	20°		
		1.6	31.5	20°		
1.8	31.5	20°				
No breakage during 20 cycles of reversal force at a rate						

Product: Spinal Needle

Zhejiang Runqiang Medical Instruments Co., Ltd

Parameter	Method	Specification																												
		of 0.5 Hz with above parameters.																												
Flow-rate through needle Spinal Needle Type II	YY0321.2-2010	For O.D. > 0.5 mm: ≥ 6 ml/min For O.D. 0.4 – 0.5 mm: ≥ 3 ml/min Flow for Spinal Needle Type II																												
Needle hub	BS 6169-1989	- With female 6% luer taper conical fitting - Tapered pin connector blocks shall comply with the requirements of ISO594-1 or ISO594-2 - No edge, plastic flow, bubbles and other defects																												
Connection between Needle and Needle Hub	YY0321.2-2010	Has to withstand: OD = 0.4 - 0.5 mm: 20 N for 10 s OD = 0.55 - 0.6 mm: 30 N for 10 s OD = 0.7 - 2.1 mm: 45 N for 10 s																												
Groove for location of the Stylet Button	-	Present																												
Needle stylet	-	<ul style="list-style-type: none"> • Consisting of button and stylet blade • Needle stylet button designed with “tongue” for fixing position with needle hub • Shall not protrude from the needle point • Shall fill the lumen of the needle completely to avoid coring 																												
Connection between Needle Stylet Button and Blade	YY0321.2-2010	Has to withstand: <ul style="list-style-type: none"> • Tensile Strength: <ul style="list-style-type: none"> OD < 0.5 mm: 5 N for 10 s OD ≥ 0.5 - 1.0 mm: 10 N for 10 s OD > 1.0 mm: 15 N for 10 s • Compressive Force: NONE 																												
Corrosion resistance (requirement for all metal parts)	ISO 9626:1991 Annex E	No visible signs of corrosion																												
Particle pollution		≥ 5 µm particles: max. 100 particles/ ml eluent																												
Colour Coding		<table border="1"> <thead> <tr> <th>Outer diameter in G</th> <th>Colour Needle Hub/ Needle Stylet Button</th> </tr> </thead> <tbody> <tr><td>27</td><td>Med-grey</td></tr> <tr><td>26</td><td>Brown</td></tr> <tr><td>25</td><td>Orange</td></tr> <tr><td>24</td><td>Purple</td></tr> <tr><td>23</td><td>Deep blue</td></tr> <tr><td>22</td><td>Black</td></tr> <tr><td>21</td><td>Dark green</td></tr> <tr><td>20</td><td>Yellow</td></tr> <tr><td>19</td><td>Cream</td></tr> <tr><td>18</td><td>Pink</td></tr> <tr><td>17</td><td>Red-purple</td></tr> <tr><td>16</td><td>White</td></tr> <tr><td>15</td><td>Blue-gray</td></tr> </tbody> </table>	Outer diameter in G	Colour Needle Hub/ Needle Stylet Button	27	Med-grey	26	Brown	25	Orange	24	Purple	23	Deep blue	22	Black	21	Dark green	20	Yellow	19	Cream	18	Pink	17	Red-purple	16	White	15	Blue-gray
Outer diameter in G	Colour Needle Hub/ Needle Stylet Button																													
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16	White																													
15	Blue-gray																													
Metal Ions	GB/T14233.1	Pb ≤ 5 µg/ml Cd ≤ 0.1 µg/ml																												
pH	GB/T14233.1	ΔpH = max. 1.0																												
EO-residuals	-	≤ 0.1mg/ml																												

Product: Spinal Needle

Zhejiang Runqiang Medical Instruments Co., Ltd

Parameter	Method	Specification
Primary Packaging		
Material	ISO 11607	Poly-Paper-Pouch: Tyvek
Dimensions	ISO 11607	197×60mm
Layout / Printing	EN 980 EN 1041	- Label printed in paper side - Accord. to latest HELM Layout - Colour: Blue (Pantone 294C) and Black - Printing is clean, straight and legible
Secondary Packaging		
Material		Paper box: ivory board
Dimensions	n/a	220×200×65mm
Layout / Printing	EN 980 EN 1041	- Accord. to latest HELM Layout - Colour: Blue (Pantone 294C) and Black - Printing is clean, straight and legible
No. of blisters in one inner carton	n/a	50 pouches/ paper box
Tertiary Packaging		
Material		Export box: Double Wall+ kraft
Dimensions	n/a	460×430×370mm
Layout / Printing	EN 980 EN 1041	- Accord. to latest HELM Layout - Colour: Blue (Pantone 294U) and Black - Printing is clean, straight and legible
No. of inner cartons in one master carton	n/a	20boxes
No. of blisters in one master carton	n/a	1000pcs

Annex 1: Product Range HELM Medical GmbH

Spinal Needle Type I

Product Specification	WWS-Code HMC	Product Code Runqiang
Spinal Needle Type I, 27G, 38mm		20001P
Spinal Needle Type I, 27G, 58mm		20002P
Spinal Needle Type I, 27G, 75mm		20003P
Spinal Needle Type I, 27G, 88mm		20004P
Spinal Needle Type I, 27G, 100mm		20005P
Spinal Needle Type I, 27G, 110mm		20006P
Spinal Needle Type I, 27G, 120mm		20007P

Spinal Needle Type I, 26G, 38mm		20008P
Spinal Needle Type I, 26G, 58mm		20009P
Spinal Needle Type I, 26G, 75mm		20010P
Spinal Needle Type I, 26G, 88mm		20011P
Spinal Needle Type I, 26G, 100mm		20012P
Spinal Needle Type I, 26G, 110mm		20013P
Spinal Needle Type I, 26G, 120mm		20014P
Spinal Needle Type I, 25G, 38mm		20015P
Spinal Needle Type I, 25G, 58mm		20016P
Spinal Needle Type I, 25G, 75mm		20017P
Spinal Needle Type I, 25G, 88mm		20018P
Spinal Needle Type I, 25G, 100mm		20019P
Spinal Needle Type I, 25G, 110mm		20020P
Spinal Needle Type I, 25G, 120mm		20021P
Spinal Needle Type I, 24G, 38mm		20022P
Spinal Needle Type I, 24G, 58mm		20023P
Spinal Needle Type I, 24G, 75mm		20024P
Spinal Needle Type I, 24G, 88mm		20025P
Spinal Needle Type I, 24G, 100mm		20026P
Spinal Needle Type I, 24G, 110mm		20027P
Spinal Needle Type I, 24G, 120mm		20028P
Spinal Needle Type I, 23G, 38mm		20029P
Spinal Needle Type I, 23G, 58mm		20030P
Spinal Needle Type I, 23G, 75mm		20031P
Spinal Needle Type I, 23G, 88mm		20032P

Spinal Needle Type I, 23G, 100mm		20033P
Spinal Needle Type I, 23G, 110mm		20034P
Spinal Needle Type I, 23G, 120mm		20035P
Spinal Needle Type I, 22G, 38mm		20036P
Spinal Needle Type I, 22G, 58mm		20037P
Spinal Needle Type I, 22G, 75mm		20038P
Spinal Needle Type I, 22G, 88mm		20039P
Spinal Needle Type I, 22G, 100mm		20040P
Spinal Needle Type I, 22G, 110mm		20041P
Spinal Needle Type I, 22G, 120mm		20042P
Spinal Needle Type I, 21G, 38mm		20043P
Spinal Needle Type I, 21G, 58mm		20044P
Spinal Needle Type I, 21G, 75mm		20045P
Spinal Needle Type I, 21G, 88mm		20046P
Spinal Needle Type I, 21G, 100mm		20047P
Spinal Needle Type I, 21G, 110mm		20048P
Spinal Needle Type I, 21G, 120mm		20049P
Spinal Needle Type I, 20G, 38mm		20050P
Spinal Needle Type I, 20G, 58mm		20051P
Spinal Needle Type I, 20G, 75mm		20052P
Spinal Needle Type I, 20G, 88mm		20053P
Spinal Needle Type I, 20G, 100mm		20054P
Spinal Needle Type I, 20G, 110mm		20055P
Spinal Needle Type I, 20G, 120mm		20056P
Spinal Needle Type I, 19G, 38mm		20057P

Spinal Needle Type I, 19G, 58mm		20058P
Spinal Needle Type I, 19G, 75mm		20059P
Spinal Needle Type I, 19G, 88mm		20060P
Spinal Needle Type I, 19G, 100mm		20061P
Spinal Needle Type I, 19G, 110mm		20062P
Spinal Needle Type I, 19G, 120mm		20063P
Spinal Needle Type I, 18G, 38mm		20064P
Spinal Needle Type I, 18G, 58mm		20065P
Spinal Needle Type I, 18G, 75mm		20066P
Spinal Needle Type I, 18G, 88mm		20067P
Spinal Needle Type I, 18G, 100mm		20068P
Spinal Needle Type I, 18G, 110mm		20069P
Spinal Needle Type I, 18G, 120mm		20070P
Spinal Needle Type I, 17G, 38mm		20071P
Spinal Needle Type I, 17G, 58mm		20072P
Spinal Needle Type I, 17G, 75mm		20073P
Spinal Needle Type I, 17G, 88mm		20074P
Spinal Needle Type I, 17G, 100mm		20075P
Spinal Needle Type I, 17G, 110mm		20076P
Spinal Needle Type I, 17G, 120mm		20077P
Spinal Needle Type I, 16G, 38mm		20078P
Spinal Needle Type I, 16G, 58mm		20079P
Spinal Needle Type I, 16G, 75mm		20080P
Spinal Needle Type I, 16G, 88mm		20081P
Spinal Needle Type I, 16G, 100mm		20082P

Spinal Needle Type I, 16G, 110mm		20083P
Spinal Needle Type I, 16G, 120mm		20084P
Spinal Needle Type I, 15G, 38mm		20085P
Spinal Needle Type I, 15G, 58mm		20086P
Spinal Needle Type I, 15G, 75mm		20087P
Spinal Needle Type I, 15G, 88mm		20088P
Spinal Needle Type I, 15G, 100mm		20089P
Spinal Needle Type I, 15G, 110mm		20090P
Spinal Needle Type I, 15G, 120mm		20091P

Spinal Needle Type II

Product Specification	WWS-Code HMC	Product Code Runqiang
Spinal Needle Type II, 27G, 75mm		30001P
Spinal Needle Type II, 27G, 88mm		30002P
Spinal Needle Type II, 27G, 100mm		30003P
Spinal Needle Type II, 27G, 110mm		30004P
Spinal Needle Type II, 27G, 120mm		30005P
Spinal Needle Type II, 26G, 75mm		30006P
Spinal Needle Type II, 26G, 88mm		30007P
Spinal Needle Type II, 26G, 100mm		30008P
Spinal Needle Type II, 26G, 110mm		30009P
Spinal Needle Type II, 26G, 120mm		30010P
Spinal Needle Type II, 25G, 75mm		30011P
Spinal Needle Type II, 25G, 88mm		30012P
Spinal Needle Type II, 25G, 100mm		30013P

Spinal Needle Type II, 25G, 110mm		30014P
Spinal Needle Type II, 25G, 120mm		30015P
Spinal Needle Type II, 24G, 75mm		30016P
Spinal Needle Type II, 24G, 88mm		30017P
Spinal Needle Type II, 24G, 100mm		30018P
Spinal Needle Type II, 24G, 110mm		30019P
Spinal Needle Type II, 24G, 120mm		30020P
Spinal Needle Type II, 23G, 75mm		30021P
Spinal Needle Type II, 23G, 88mm		30022P
Spinal Needle Type II, 23G, 100mm		30023P
Spinal Needle Type II, 23G, 110mm		30024P
Spinal Needle Type II, 23G, 120mm		30025P
Spinal Needle Type II, 22G, 75mm		30026P
Spinal Needle Type II, 22G, 88mm		30027P
Spinal Needle Type II, 22G, 100mm		30028P
Spinal Needle Type II, 22G, 110mm		30029P
Spinal Needle Type II, 22G, 120mm		30030P
Spinal Needle Type II, 21G, 75mm		30031P
Spinal Needle Type II, 21G, 88mm		30032P
Spinal Needle Type II, 21G, 100mm		30033P
Spinal Needle Type II, 21G, 110mm		30034P
Spinal Needle Type II, 21G, 120mm		30035P
Spinal Needle Type II, 20G, 75mm		30036P
Spinal Needle Type II, 20G, 88mm		30037P
Spinal Needle Type II, 20G, 100mm		30038P

Spinal Needle Type II, 20G, 110mm		30039P
Spinal Needle Type II, 20G, 120mm		30040P

Appendix II: Technical Drawings

Spinal Needle Type I:

Doc name	Drawings of product of anesthesia needle and anesthesia kit	Doc No	CEAS -01-10
Version	A/0	Effective date	2012-04-30

00-2- I S-NV

Technical requirements:

1. Needle tube and Hub Connected together straight, tension test $\geq 20N$.
2. Needle tip and Hub in the same plane positioning.
3. According to the standard of YY0321.2-2009.

L1	L2	L3
38 ± 1	53 ± 1	100 ⁺¹ ₋₂
58 ± 1	73 ± 1	100 ⁺¹ ₋₂
75 ± 1	90 ± 1	100 ⁺¹ ₋₂
98 ± 1	103 ± 1	100 ⁺¹ ₋₂
100 ± 1	115 ± 1	130 ⁺¹ ₋₂
110 ± 1	125 ± 1	130 ⁺¹ ₋₂
120 ± 1	135 ± 1	130 ⁺¹ ₋₂

7	AN-S I -1-07	Sheath	1	PP	
6	AN-S I -1-06	Stylet blade	1	0Cr18Ni9	
5	AN-S I -1-05	Protect tube	1	0Cr18Ni9	
4	AN-S I -1-04	Choke plug	1	ABS	
3	AN-S I -1-03	Button	1	ABS	
2	AN-S I -2-01	Hub	1	K-resin	
1	AN-S I -1-01	Needle tube	1	0Cr18Ni9	

Tracing					
Past Base map No.					
Base map No.					
Date Signature					

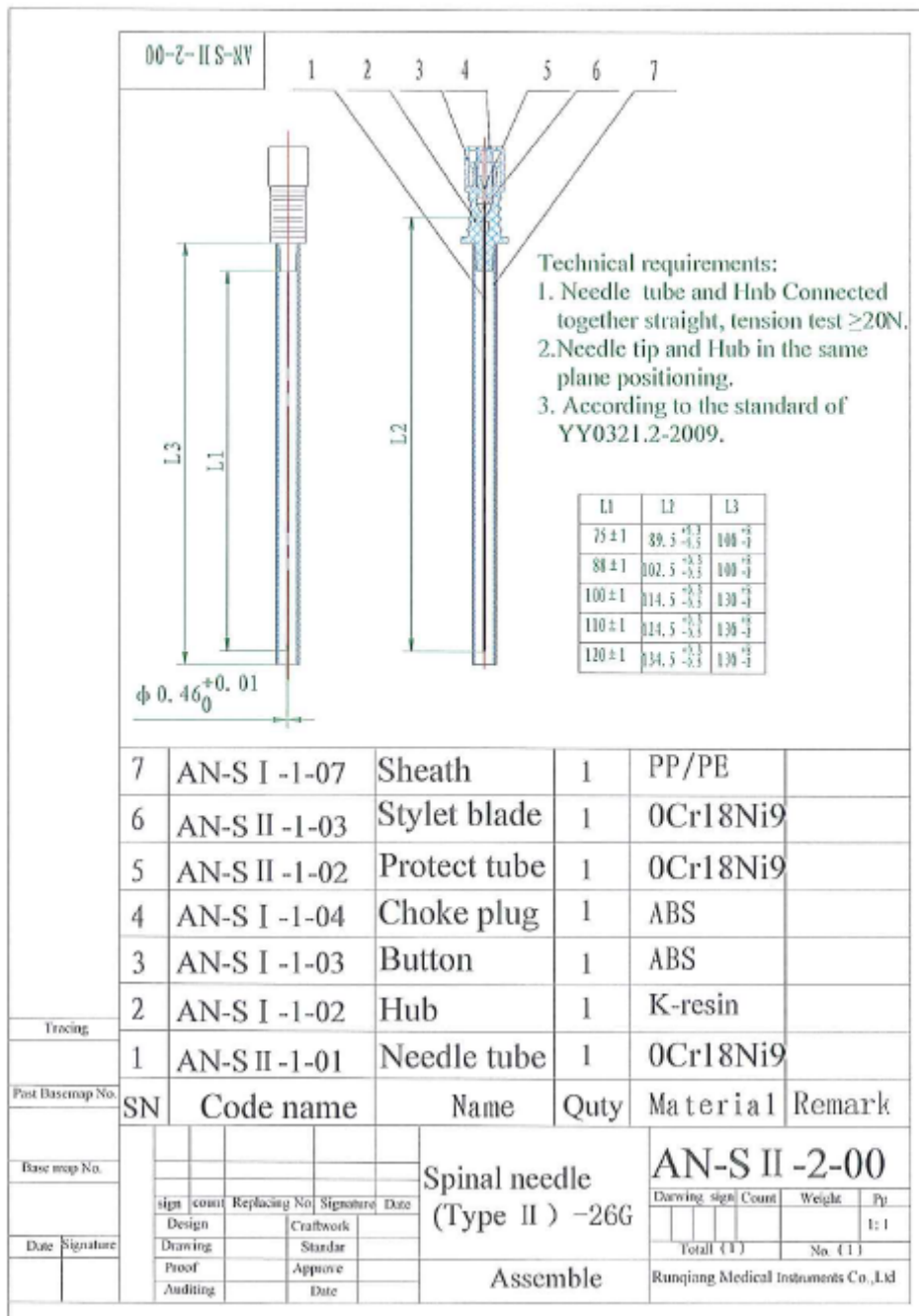
SN	Code name	Name	Qty	Material	Remark
Spinal needle (Type I) -26G					
Assemble					

AN-S I -2-00			
Drawing sign	Count	Weight	Pp
			: 1
Total (1)		No. (1)	
Runjiang Medical Instruments Co.,Ltd			

Remark: Lengths parameters, including tolerances, are valid for all Gauge-sizes!

Spinal Needle Type II:

Doc name	Drawings of product of anesthesia needle and anesthesia kit	Doc No	CE/AS -01-10
Version	A/0	Effective date	2012-04-30



Remark: Lengths parameters, including tolerances, are valid for all Gauge-sizes!