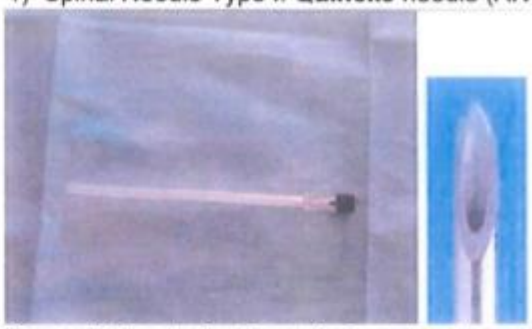
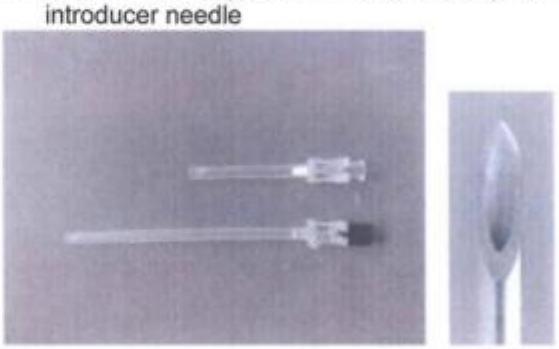
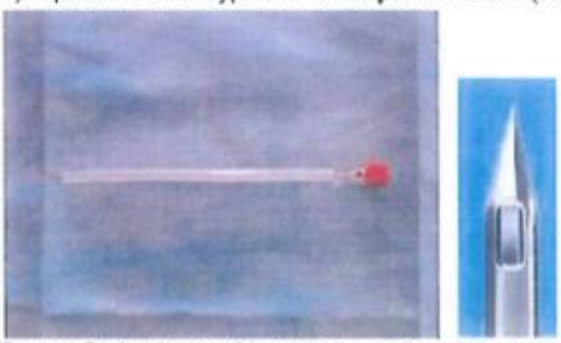
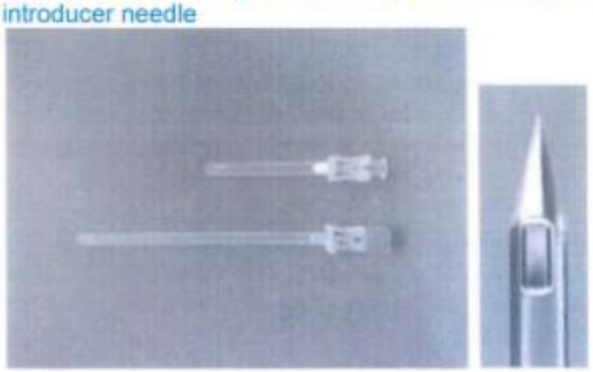
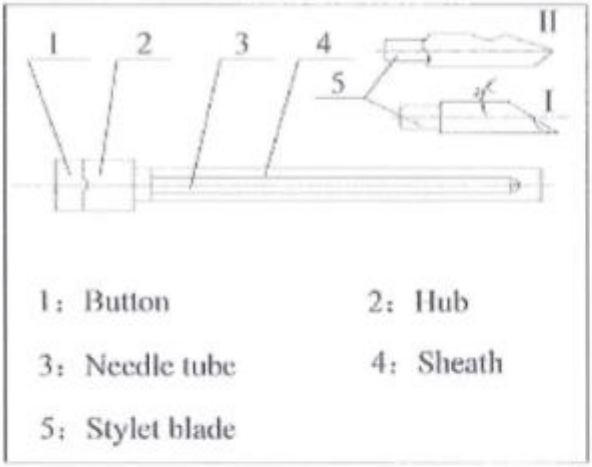
Product Description	-	The product spinal needle is made up of three parts: - Spinal needle (needle tube + needle hub) - Stylet (stylet blade + button) - Sheath Spinal needles 25 G – 27 G are available with / without introducer needle (optional). **2 different types** of spinal needles available: 1) Spinal Needle Type I: **Quincke** needle (AN-SI)  [**Source:** Design dossier of anaesthesia needle and anaesthesia kit CE/AS-01-01 Zhejiang Runqiang Medical Co., Ltd.) 1.2 Spinal Needle Type I: **Quincke** needle (AN-SI) + introducer needle  [**Source:** Design dossier of anaesthesia needle and anaesthesia kit CE/AS-01-01 Zhejiang Runqiang Medical Co., Ltd.) 2) Spinal Needle Type II: **Pencil point** needle (AN-SII)  [**Source:** Design dossier of anaesthesia needle and anaesthesia kit

		CE/AS-01-01 Zhejiang Runqiang Medical Co., Ltd.) 2.1) Spinal Needle Type II: **Pencil point** needle (AN-SII) + introducer needle  [**Source:** Design dossier of anaesthesia needle and anaesthesia kit CE/AS-01-01 Zhejiang Runqiang Medical Co., Ltd.)
Intended Use	MDD 93/42/EEC	For clinical use in the subarachnoid cavity block for anaesthesia. For puncture/ injection in the human body.
Risk Class	MDD 93/42/EEC	Class III
Rule	Annex IX	Rule 6
UMDNS-Code	-	12753
Parameter	**Method**	**Specification**
Sterility	EN ISO 11135-1 EN ISO 11737-1 EN ISO 11737-2	Sterile by EO Gas
Biocompatibility	EN ISO 10993-1	Category: External communicating device Contact: Tissue/bone/dentin Contact Duration: A-limited (≤24h)
Cytotoxicity	EN ISO 10993-5	Product + packaging: Viability ≥ 70 %
Sensitization	EN ISO 10993-10	Product + packaging: No visible change
Irritation or intracutaneous reactivity	EN ISO 10993-10	Product + packaging: No erythema, no oedema
Acute Systemic Toxicity	EN ISO 10993-11	Product: Normal, no symptoms
Bacterial Endotoxins	GB/T14233.1	< 2.15 EU/product
EO-Residuals	EN ISO 10993-7	< 0.1 mg/ ml
Limits for acidity and alkalinity	EN ISO 9626 Annex A	≥ 0.04 ml Sodium Hydroxide or ≥ 0.12 ml Hydrochloric Acid
Metal Ions	GB/T14233.1	Pb ≤ 5 µg/ml Cd ≤ 0.1 µg/ml
pH	GB/T14233.1	ΔpH = max. 1.0
Shelf Life	EN ISO 11607-1 EN ISO 11607-2	2 years

Storage Conditions	EN ISO 11607	1. Not allowed to pressed under heavy load 2. No direct sun 3. To be stored dry (away from rain and snow) 4. Soft handling during transportation 5. Stored in cool, dry (humidity < 80%), well-ventilated and clean place 6. Stored free of caustic gases

II. Components



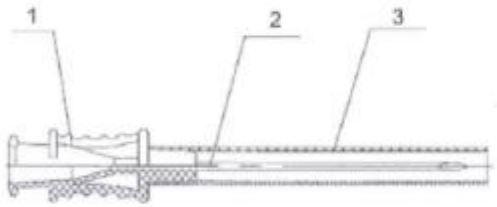
1：Button　　2：Hub

3：Needle tube　　4：Sheath

5：Stylet blade

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

Optional: Introducer needle



1. Hub 2.Needle tube 3.Protective sheath.

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

Name of component	**Material**	**Specification/ Degree**
Spinal needle	304 stainless steel	Needle tube (3) & stylet blade (5)
	K-resin	Hub (2)
	ABS	Button (1)
	PP	Sheat (4)
Introducer needle	304 stainless steel	Needle tube (2)
	K-resin	Hub (1)
	PP	Sheat (3)
Parameter	**Method**	**Specification**
L1 Effective needle length in mm **L2 Overall needle length in mm**	YY0321.2-2010	**Spinal Needle Type I:** **L1 (+/- 1mm)** / **L2 (+/- 1mm)** / **L3 (+ 8/ - 2mm)**

L3 Sheath length in mm

(Definition of L1, L2, L3 see Appendix II: Technical Drawings)

38	53	100
58	73	100
75	90	100
88	103	100
100	115	130
110	125	130
120	135	130

Spinal Needle Type II:

L1 (+/- 1mm)	L2 (+ 0.3/ - 0.5mm)	L3 (+ 8/ - 2mm)
75	89.5	100
88	102.5	100
100	114.5	130
110	124.5	130
120	134.5	130

Introducer Needle:

Effective length (+/- 1mm)	Overall length (+/- 1mm)	Sheat length (+/- 1mm)
38	68.2	48

Outer diameter needle tube in G/ mm

EN ISO 9626

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

Introducer Needle

OD in G	OD in mm	OD Tolerances in mm
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 EN ISO 9626 Spinal Needle Type I

<table>
<tr>
<td>L3 Sheath length in mm

(Definition of L1, L2, L3 see Appendix II: Technical Drawings)</td>
<td></td>
<td>
<table>
<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>
</table>
Spinal Needle Type II:
<table>
<tr><th>L1
(+/- 1mm)</th><th>L2
(+ 0.3/ - 0.5mm)</th><th>L3
(+ 8/ - 2mm)</th></tr>
<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>
<tr><td>110</td><td>124.5</td><td>130</td></tr>
<tr><td>120</td><td>134.5</td><td>130</td></tr>
</table>
Introducer Needle:
<table>
<tr><th>Effective length
(+/- 1mm)</th><th>Overall length
(+/- 1mm)</th><th>Sheat length
(+/- 1mm)</th></tr>
<tr><td>38</td><td>68.2</td><td>48</td></tr>
</table>
</td>
</tr>
<tr>
<td>Outer diameter needle tube in G/ mm</td>
<td>EN ISO 9626

In mm to the nearest 0.05mm for O.D. < 0.6mm

In mm to the nearest 0.1mm for O.D. ≥ 0.6mm</td>
<td>
Spinal Needle Type I
<table>
<tr><th>OD in G</th><th>OD in mm</th><th>OD Tolerances in mm</th></tr>
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<tr><td>15</td><td>1.8</td><td>1.750-1.900</td></tr>
</table>
Spinal Needle Type II
<table>
<tr><th>OD in G</th><th>OD in mm</th><th>OD Tolerances in mm</th></tr>
<tr><td>27</td><td>0.4</td><td>0.400-0.420</td></tr>
<tr><td>26</td><td>0.45</td><td>0.440-0.470</td></tr>
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<tr><td>20</td><td>0.9</td><td>0.860-0.920</td></tr>
</table>
Introducer Needle
<table>
<tr><th>OD in G</th><th>OD in mm</th><th>OD Tolerances in mm</th></tr>
<tr><td>22</td><td>0.7</td><td>0.698-0.730</td></tr>
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<tr><td>20</td><td>0.9</td><td>0.860-0.920</td></tr>
</table>
</td>
</tr>
<tr>
<td>Inner diameter needle tube</td>
<td>EN ISO 9626</td>
<td>Spinal Needle Type I</td>
</tr>
</table>

<table>
<tr><td></td><td></td><td>
<table>
<tr><td>0.6</td><td>12.5</td><td>10</td><td>0.45</td></tr>
<tr><td>0.7</td><td>15</td><td>10</td><td>0.50</td></tr>
<tr><td>0.8</td><td>15</td><td>15</td><td>0.50</td></tr>
<tr><td>0.9</td><td>17.5</td><td>15</td><td>0.65</td></tr>
<tr><td>1.1</td><td>25</td><td>10</td><td>0.55</td></tr>
<tr><td>1.2</td><td>25</td><td>20</td><td>0.55</td></tr>
<tr><td>1.4</td><td>25</td><td>22</td><td>0.55</td></tr>
<tr><td>1.6</td><td>25</td><td>22</td><td>0.30</td></tr>
<tr><td>1.8</td><td>25</td><td>25</td><td>0.45</td></tr>
</table>
</td></tr>
<tr><td>Needle toughness/ resistance to breakage</td><td>EN ISO 9626 Annex D</td><td>
<table>
<tr><th>Designated metric size in mm</th><th>Distance between rigid support and point of application of bending force in mm +/- 0.1</th><th>Bending Angle</th></tr>
<tr><td>0.4</td><td>8</td><td>20°</td></tr>
<tr><td>0.45</td><td>10</td><td>20°</td></tr>
<tr><td>0.5</td><td>10</td><td>20°</td></tr>
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<tr><td>1.8</td><td>31.5</td><td>20°</td></tr>
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No breakage during 20 cycles of reversal force at a rate of 0.5 Hz with above parameters.
</td></tr>
<tr><td>Flow-rate through needle Spinal Needle Type II

For Spinal Needle Type I and Introducer Needle not defined & required</td><td>YY0321.2-2010</td><td>For O.D. > 0.5 mm: ≥ 6 ml/min
For O.D. 0.4 – 0.5 mm: ≥ 3 ml/min</td></tr>
<tr><td>Needle hub</td><td>BS 6169</td><td>- 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</td></tr>
<tr><td>Connection between Needle and Needle Hub</td><td>YY0321.2-2010</td><td>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
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<tr><td>Groove for location of the Stylet Button</td><td>-</td><td>Present</td></tr>
<tr><td>Needle stylet</td><td>-</td><td>• 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</td></tr>
</table>

		coring
Connection between Needle Stylet Button and Blade	YY0321.2-2010	Has to withstand: • Tensile Strength: 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)	EN ISO 9626 Annex E	No visible signs of corrosion
Particle pollution	-	≥ 5 µm particles: max. 100 particles/ ml eluent
Colour Coding	-	

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

III. Packaging

a. Variable Data

Format Manufacturing date	YYYY/MM
Format Expiry Date	YYYY/MM
Batch number system	• 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

b. Packing Details

No. of Pouches in one Export Carton	1000
No. of Clinic Cartons in one Export Carton	20
No. of Pouches in one Clinic Carton	50

c. Primary packaging

Name of component	Material	Method(s)	Specification and degree
Poly-Paper-Pouch	PE-Bag with Tyvek Paper	EN ISO 11607	-
Layout primary packaging		EN 980 EN 1041	- Label printed on paper side - Accord. to latest HELM Layout - Printing is clean, straight and legible
Colour		EN 980 EN 1041	Blue (Pantone 294C) and Black
Dimensions (LxW) [mm]		EN ISO 11607	197 x 60 mm

d. Secondary packaging

Name of component	Material	Method(s)	Specification and degree
Clinic Carton	Paper box	-	Ivory board
Layout secondary packaging		EN 980 EN 1041	- Accord. to latest HELM Layout - Printing is clean, straight and legible
Colour		EN 980 EN 1041	Blue (Pantone 294U) and Black
Dimensions (LxWxH) [mm]		EN ISO 11607	220 x 200 x 65 mm

e. Tertiary packaging

Name of component	Material	Method(s)	Specification and degree
Export Carton	Double Wall+ Kraft	-	-
Layout tertiary packaging		EN 980 EN 1041	- Accord. to latest HELM Layout - Printing is clean, straight and legible
Colour		EN 980 EN 1041	Blue (Pantone 294U) and Black
Dimensions (LxWxH) [mm]		EN ISO 11607	460 x 430 x 370 mm

<table>
<tr><td></td><td></td><td>
<table>
<tr><td>0.6</td><td>12.5</td><td>10</td><td>0.45</td></tr>
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Manufacturer: Zhejiang Runqiang Medical Instruments Co., Ltd. **WWS Code: See Annex 1**

		coring
Connection between Needle Stylet Button and Blade	YY0321.2-2010	Has to withstand: • Tensile Strength: 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)	EN ISO 9626 Annex E	No visible signs of corrosion
Particle pollution	-	≥ 5 µm particles: max. 100 particles/ ml eluent
Colour Coding	-	**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

III. Packaging

a. Variable Data

Format Manufacturing date	YYYY/MM
Format Expiry Date	YYYY/MM
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b. Packing Details

No. of Pouches in one Export Carton	1000
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No. of Pouches in one Clinic Carton	50

c. Primary packaging

Name of component	**Material**	**Method(s)**	**Specification and degree**
Poly-Paper-Pouch	PE-Bag with Tyvek Paper	EN ISO 11607	-
Layout primary packaging		EN 980 EN 1041	- Label printed on paper side - Accord. to latest HELM Layout - Printing is clean, straight and legible
Colour		EN 980 EN 1041	Blue (Pantone 294C) and Black
Dimensions (LxW) [mm]		EN ISO 11607	197 x 60 mm

d. Secondary packaging

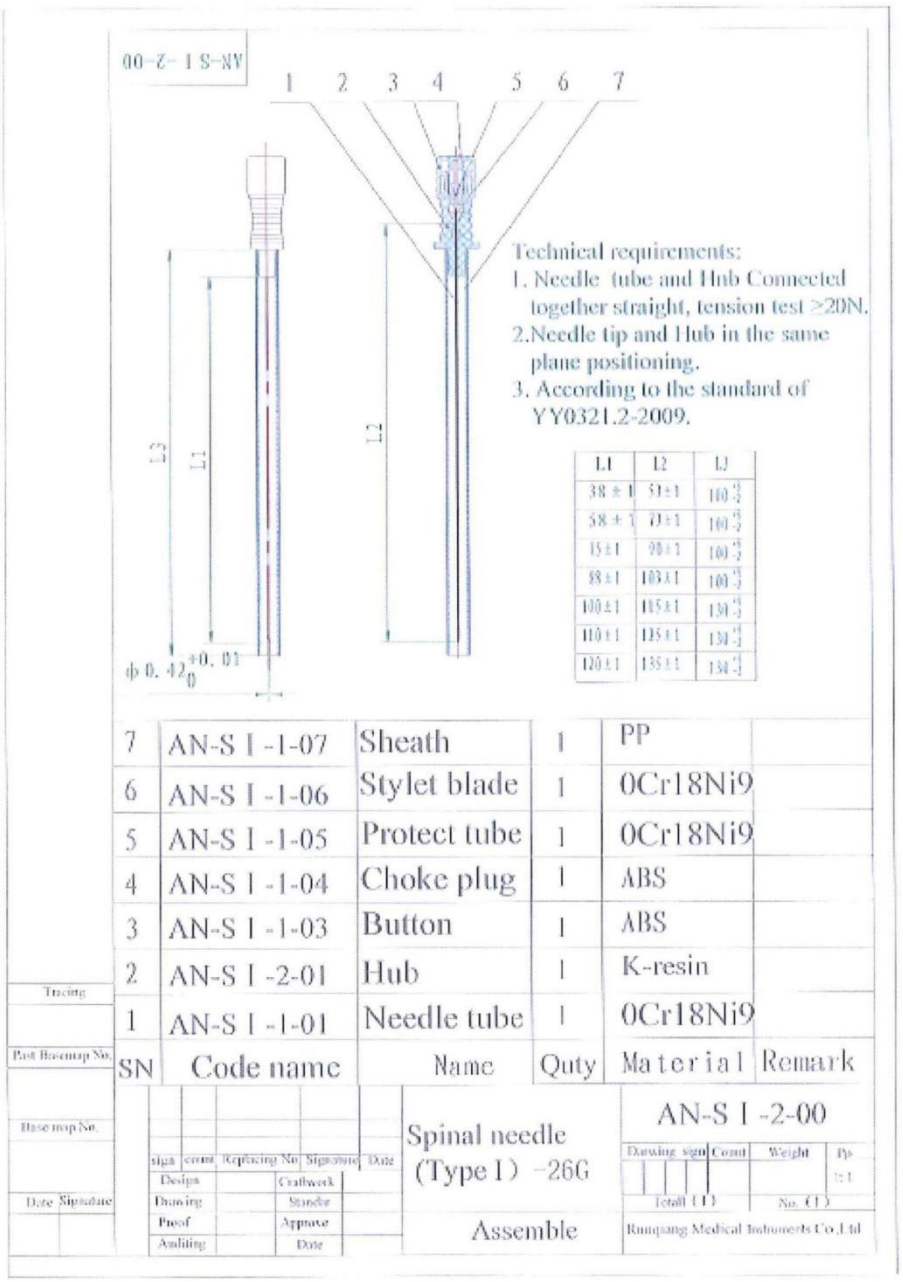
Manufacturer: Zhejiang Runqiang Medical Instruments Co., Ltd. **WWS Code: See Annex 1**

Name of component	Material	Method(s)	Specification and degree
Clinic Carton	Paper box	-	Ivory board
Layout secondary packaging		EN 980 EN 1041	- Accord. to latest HELM Layout - Printing is clean, straight and legible
Colour		EN 980 EN 1041	Blue (Pantone 294U) and Black
Dimensions (LxWxH) [mm]		EN ISO 11607	220 x 200 x 65 mm
e. Tertiary packaging			
Name of component	**Material**	**Method(s)**	**Specification and degree**
Export Carton	Double Wall+ Kraft	-	-
Layout tertiary packaging		EN 980 EN 1041	- Accord. to latest HELM Layout - Printing is clean, straight and legible
Colour		EN 980 EN 1041	Blue (Pantone 294U) and Black
Dimensions (LxWxH) [mm]		EN ISO 11607	460 x 430 x 370 mm

IV. Technical drawing

Example Drawing Spinal Needle Type I:

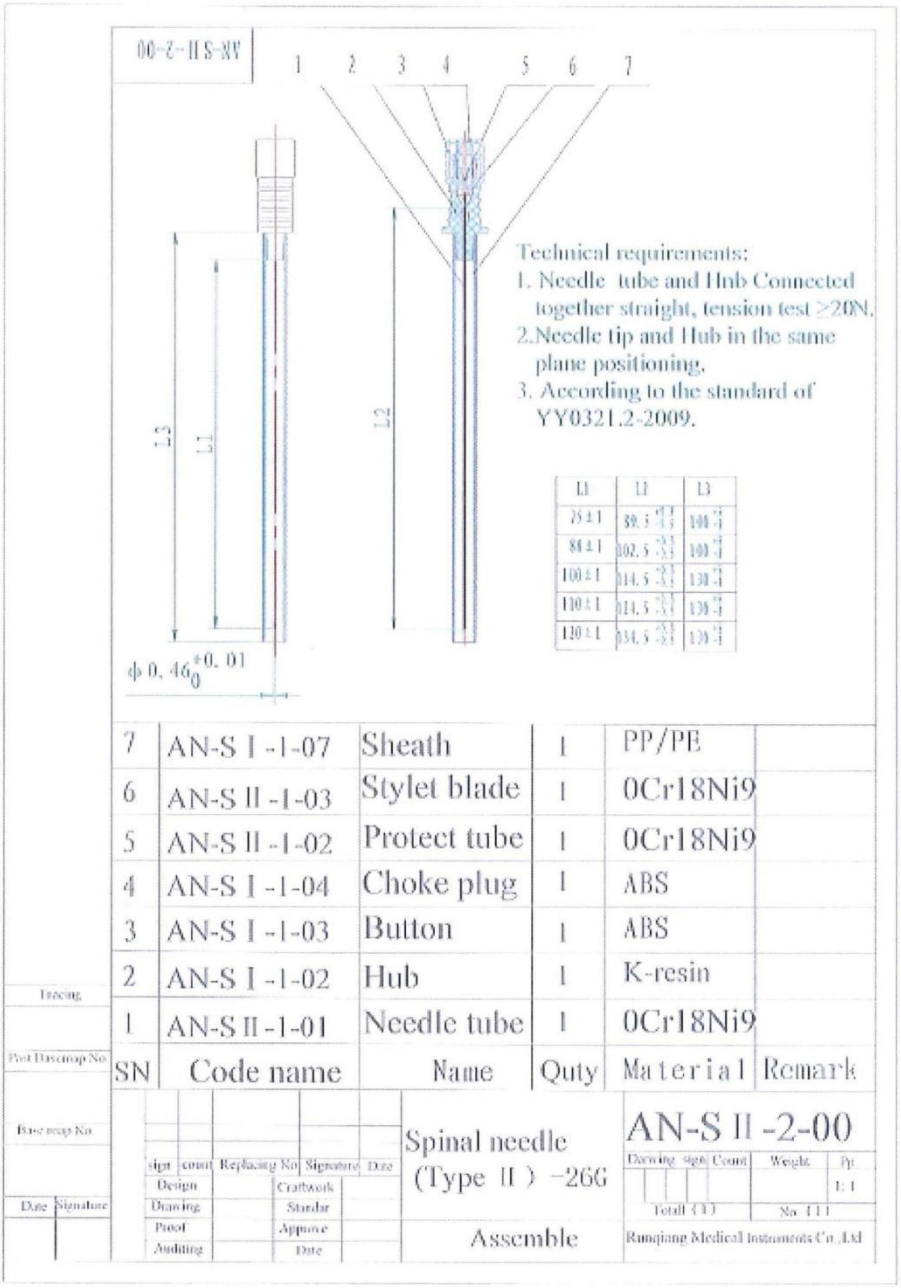
Doc name	Drawings of product of anesthesia needle and anesthesia kit	Doc No	CEAS-01-10
Version	A/0	Effective date	2012-04-30



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

Example Drawing 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!

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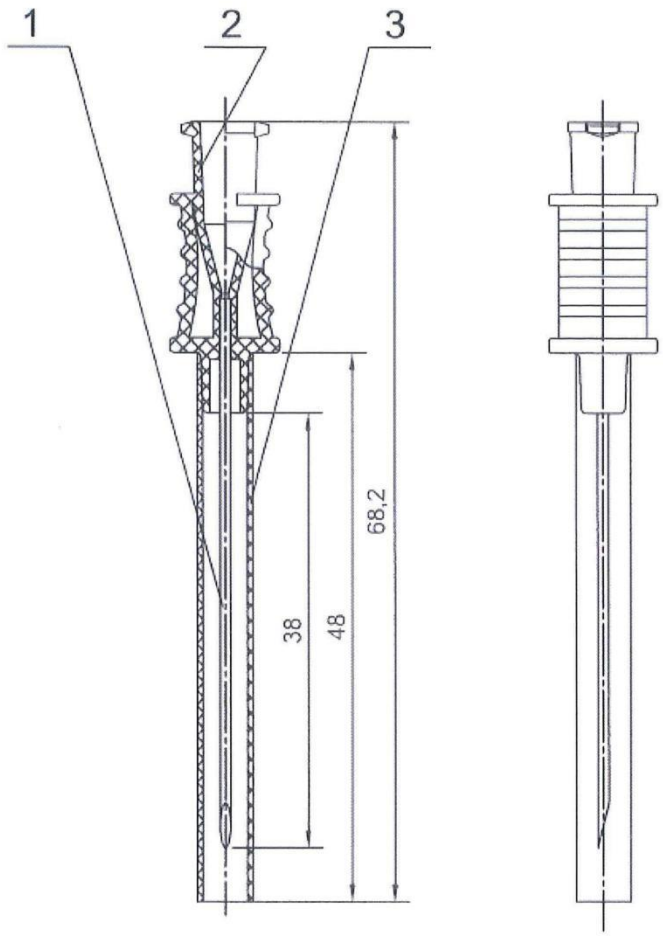
Example Drawing Introducer Needle:



38 mm = Effective Length
68.2 mm = Overall Length
48 mm = Sheet Length