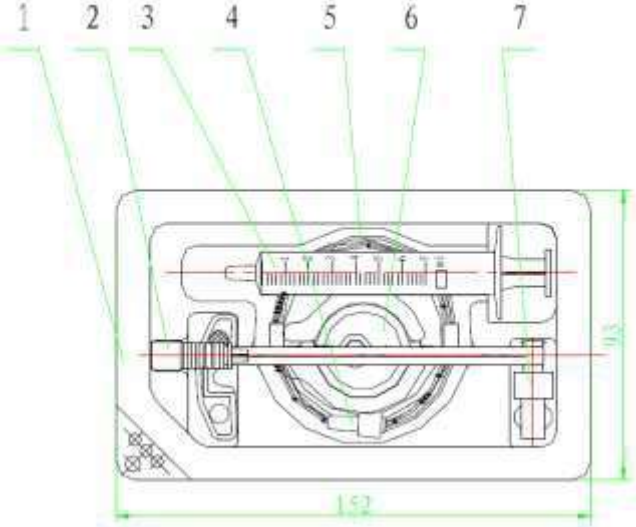


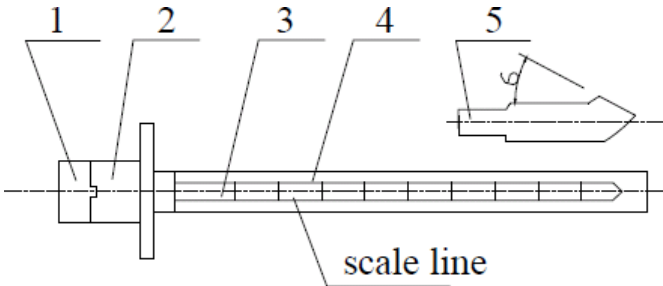
Zhejiang Runqiang Medical Instruments Co., Ltd

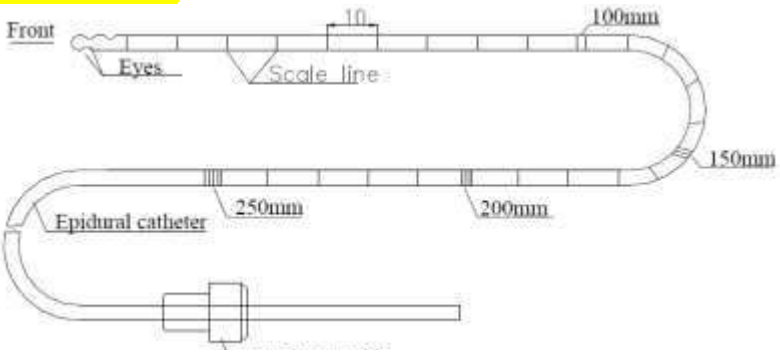
Add: No. 599 Ruifeng Street, Gaozhao District, Xiuzhou District, 314031 Jiaxing City, Zhejiang Province, CHINA

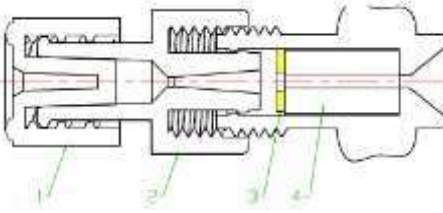
I. General		
Product Description	REF 140043B -16G REF 40083B -17G REF 40103B -18G	Epidural Kit including following components: - Epidural Catheter with introducer guide - Epidural Needle (Tuohy type) - Catheter connector (Luer Lock) - Introducer guide - Filter - LOR syringe
Intended Use	MDD 93/42/EEC	For clinical use in the field of anaesthesia. For puncture of and injection into the human body.
Risk Class	MDD 93/42/EEC	III
Rule	Annex IX	7
UMDNS-Code	-	10-127
Parameter	Method	Specification
Sterility	EN ISO 11135 EN ISO 11737-2	Sterile by EO Gas
Biocompatibility	EN ISO 10993-1	External device with indirect contact to blood circulation system. To be used up to 30 days.
Cytotoxicity (for product & packaging material)	EN ISO 10993-5	Viability > 70 %
Sensitization (for product & packaging material)	EN ISO 10993-10	≤ Grade 1
Irritation (for product & packaging material)	EN ISO 10993-10	Test extract score: ≤ 1.0
Acute Systemic Toxicity	EN ISO 10993-11	Normal, no symptoms
Haemocompatibility	EN ISO 10993-4	Haemolysis rate < 5 %
Bacterial Endotoxins	GB/T14233.2	< 20 EU/product
EO-Residuals	EN ISO 10993-7	≤ 10 µg/g
Reduction material	EN ISO 10993-18	2.0ml/20ml
pH value	EN ISO 10993-18	≤ 1.0
Heavy metal	EN ISO 10993-18	Pb, Zn, Sn, Fe ≤ 5 µg/ml Cd ≤ 0.1 µg/ml
Shelf Life	EN ISO 11607-1	5 years
Storage Conditions	EN ISO 11607	<ul style="list-style-type: none"> • Not allowed to be 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

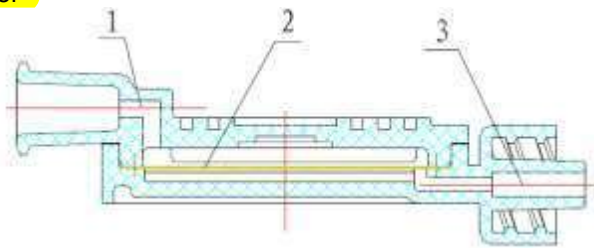
II. Components

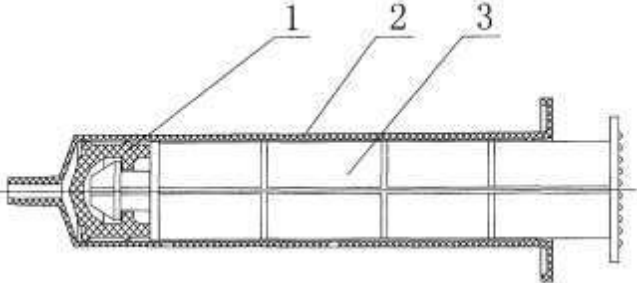
 <p>Ref. Runqiang Doc. No. CE/AS -01-10</p>	<ul style="list-style-type: none"> • Packing Tray • Epidural Needle • LOR Syringe • Introducer Guide • Epidural Catheter • Filter • Catheter Connector
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Name of component		Material	Specification/ Degree
Epidural Needle (Tuohy type)  Ref. Runqiang Doc. No. CE/AS-01-01		Needle tube: AISI 304 stainless steel Needle hub: K-resin (Styrene-Butadiene Copolymers) #CAS 9003-55-8 Stylet blade: Polypropylene (PP) #CAS 9003-07-0 Stylet button: Polypropylene (PP) #CAS 9003-07-0 Dye: Polypropylene (PP) or Polyethylene (PE) #CAS Wuxi Changhong Masterbatches Co., Ltd. Needle cap: Polypropylene (PP) #CAS 9003-07-0	1. Button 2. Hub 3. Needle tube 4. Needle cap 5. Needle stylet
Parameter	Method	Specification	
Effective needle length in mm	BS6196	80mm: 0.75 – 0.84 90mm: 0.85 – 0.94	
Overall needle length in mm	BS6196	105mm: 104.5 – 105.4 115mm: 114.5 – 115.4	
O.D. needle tube in G / mm	BS6196	In G	In mm
		15	1.82 (1,81 – 1,83)
		16	1.66 (1,65 – 1,67)
		17	1.47 (1,46 – 1,48)
		18	1.28 (1,27 – 1,29)
Markings	BS6196	The needle tube shall be marked with distance bands which shall be 10 mm apart and shall originate from the hub	
Needle tube	BS6196	- straight - regular cross section - regular wall thickness - free from defects - smooth	
		- no impurities - should be parallel: Deviation max. +/- 15°	
Needle point	BS6196	- no cutting edges around inner aspect of the bevel - tip should be burr free, no flat head and no hook - Angle of bended tip 8° (6-10°)	
Needle hub	BS6196	- With female 6% luer taper conical fitting - With groove for location of the Stylet Button - Quadrilateral	
Connection between Needle and Needle Hub	BS 6169 Appendix F	Has to withstand: 60N for 5s (at 100 mm/min)	
Wings	BS 6169 Figure 2	- Shall fit on the hub - Axis A and B shall be parallel within a tolerance of ± 15° - Fixed wings	
Needle Stylet	-	- 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 - Shall not fall out of the epidural introducer needle under its own weight	

Connection between Needle Stylet Button and Blade	BS6196 Appendix F	Has to withstand: - Tensile Strength: 10N for 5s (at 100mm/min) - Compressive Force: 5N for 5s (at 100mm/min)	
Corrosion resistance (requirement for all metal parts)	BS6196 Appendix E	No visible signs of corrosion	
Component Weight with tolerances		- 2.2g +/- 0.5g	
Name of component		Material	Specification/ Degree
Epidural Catheter and Introducer Guide  Ref. Runqiang Doc. No. CE/AS-01-01		Epidural Catheter: Polyamid (PA) #CAS 63428-84-2 Ink: Marabu-TPU #CAS Introducer Guide: Acrylonitrile butadiene styrene (ABS) #CAS 97048-04-9 Dye: Polypropylene (PP) or Polyethylene (PE)	-
Parameter	Method	Specification	
O.D. of catheter in mm	BS 6169 OD expressed in mm to the nearest 0.1 mm	Needle size	O.D. of catheter (tolerances)
		15G	1.0 mm (0.95-1.05)
		16G	1.0 mm (0.95-1.05)
		17G	0.8 mm (0.75-0.85)
		18G	0.8 mm (0.75-0.85)
Effective length (excl. hub) in mm	BS 6169	≥ 900mm	
Appearance + markings	BS 6169	- Smooth and clear - Permanently marked with graduations at 10 mm intervals from 50 mm to 100 mm from the tip of the patient end - 100 mm, 150 mm and 200 mm intervals marked with double, triple and quadruple bands. - Distance indicator marks shall be visible from all aspects. - Phase water/ air has to be visible inside the catheter tube at any time	
Catheter tip	BS 6169	Closed and rounded	
Eyes	BS 6169	- Three lateral eyes not more than 20mm from the tip - Smooth edges	
Radiolucent	DIN 13273-8	Catheter equipped with x-ray contrast line	
Break force	DIN 13273-8	Has to withstand a force of >=10N (at 200 mm/min)	

Introducer Guide	ISO 594-1	<ul style="list-style-type: none">- Shall fit in the hub of the epidural needle- Shall be free from particles and extraneous matter- Shall be free from any defects like raw edges, burrs and plastic flow- Has to avoid the bending of the catheter	
Tightness of the overall assembled system	DIN 13273-8/ EN ISO 10555-1 Annex C	No leakage at connections from/ to catheter	
Consistency of the catheter	DIN 13273-8	Passing of distilled water or deionized water through the catheter has to be assured	
Fitting of Catheter and Needle	DIN 13273-8	Insertion and movement of the catheter inside the needle has to be assured.	
Component Weight with tolerances	-	1.1g +/- 0.1g	
Name of component		Material	Specification/ Degree
<div>Catheter Connector</div>  <div>Ref. Runqiang Doc. No. CE/AS-01-01</div>		Acrylonitrile butadiene styrene (ABS) #CAS 97048-04-9 Synthetic Rubber #CAS Guangzhoushiru ihe Silicone rubber Science and technology Co., Ltd.Dye: Polypropylene (PP) or Polyethylene (PE)	<div><div>1. Cover</div><div>2. Tie-in cover</div><div>3. Tie in</div><div>4. Housing</div></div>
Parameter	Method	Specification	
Fitting	BS 6196	<ul style="list-style-type: none">- female 6 % (Luer) taper conical fitting- with closure- Separate variants for 0.8 mm and 1.0 mm epidural catheter	
Connection between catheter and connector	DIN 13273-8	Shall not loosen at 5N for 2min	
Component Weight with tolerances	-	1.3g +/- 0.1g	

Name of component		Material	Specification/ Degree
<p>Filter</p>  <p>Ref. Runqiang Doc. No. CE/AS-01-01</p>		<p>Housing with luer-slip connector: Acrylonitrile butadiene styrene (ABS)</p> <p>Filter film:)Polyester (PES) #CAS 113669-97-9 #CAS 97048-04-9</p> <p>Housing with luer-lock connector:)Polyester (PES) #CAS 113669-97-9</p>	<ol style="list-style-type: none"> 1. Housing with luer-slip connector 2. Filter film 3. Housing with luer-lock connector
Parameter	Method	Specification	
Pore diameter	-	0.2 µm	
Appearance	YY0321.3 ISO 594-1/ ISO 594-2	<ul style="list-style-type: none"> - Free from edges, burrs and particles - With female 6% luer taper conical fitting - Hub shall have protection cap 	
Flowrate	YY0321.3	0,9% NaCl solution at 300kPa shall not be less than 200 ml/min	
Filter percentage	YY0321.3	Retention of latex particles on the fluid filter shall be not less than 90%.	
Leakage	YY0321.3	No sign of leakage.	
Particle contamination	YY0321.3 Annex D	Number of particles of 5.0µm shall not exceed 100pcs/ml in 60ml eluent.	
Flow of connected system	DIN 13273-8	When catheter, connector and filter are connected free flow of distilled deionized water must be granted	
Component Weight with tolerances	-	4.6g +/- 0.2g	

Name of component		Material	Specification
LOR-Syringe (3-Parts)  Ref. Runqiang Doc. No. CE/AS-01-01		Plunger: Polypropylene (PP) #CAS 9003-07-0 Dye: Polypropylene (PP) or Polyethylene (PE) #CAS Wuxi Changhong Masterbatches Co., Ltd. Barrel: Polypropylene (PP) #CAS 9003-07-0 Dye: Polypropylene (PP) or Polyethylene (PE) #CAS Wuxi Changhong Masterbatches Co., Ltd. Piston: Synthetic rubber #CAS Guangzhoushiruihe Silicone rubber Science and technology Co., Ltd.	1. Plunger 2. Piston 3. Barrel
Parameter	Method	Specification	
Nominal Volume	EN ISO 7886-1	5 ml / 10 ml	
Graduated Volume	EN ISO 7886-1	6 ml	
Total Length	-	100 mm	
Ø Diameter	-	15,4 mm	
Appearance	EN ISO 7886-1	- Free from edges, burrs and particles - With female 6% luer taper conical fitting - Hub shall have protection cap	
Limits for acidity or alkalinity	EN ISO 7886-1	pH value of an extract prepared in accordance with annex A shall be within one unit of pH of that to the control fluid.	
Limits for extractable Metals	EN ISO 7886-1	Contains not more than a combined total of 5mg/l of lead, tin, zinc and iron. Cadmium content lower than 0.1mg/l.	
Lubricant	EN ISO 7886-1	Lubricant shall not be visible as drops or particles	
Tolerance on graduated capacity	EN ISO 7886-1	Tolerance graduated volume: +/- 4 %	
Graduated scale	EN ISO 7886-1	0.2 ml graduated volume steps	
Numbering of scale	EN ISO 7886-1	Each 1 ml step identified by scaling number	
Overall length of scale to nominal capacity line	EN ISO 7886-1	Min. 36 mm	
Position of scale	EN ISO 7886-1	< 0.125 ml	
Handle plates	EN ISO 7866-1	- Have to be available at the end of the cylinder and handy - Have to prevent the syringe from rolling (not more than 180° on a 10° slope) - Have to be free of grates and sharp edges	
Plunger	EN ISO 7886-1	- To be movable by medium hand force - Minimum length of 12.5 mm - The piston shall not move under its own weight (under wet conditions) - Plunger end has to be in contact with inner surfaces of barrel	

Taper connection	ISO 594-1 EN ISO 7886-1	- Luer-connector - Centralized - Inner diameter > 1.2 mm
Dead space	EN ISO7886-1 Annex C	≤ 0.075 ml
(Air—and liquid) leakage	EN ISO 7886-1 Annex B + D	Annex B: Under suction - No leakage between piston and barrel - No disconnection of piston and barrel Annex D: Under pressure - No leakage under 2.0 N (+/- 5%) and 300 kPa (+/- 5%)
Component Weight with tolerances	-	9.1g +/- 0.2g

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 Blisters in one Export Carton	100
No. of Clinic Boxes in one Export Carton	10
No. of Blisters in one Clinic Carton	10

c. Primary packaging

Name of component	Material	Method(s)	Specification and degree
Blister	PVC Dupont Tyvek	EN ISO 11607	<u>Suck Plastic Box</u> consisting of tray and dialyzing paper
Layout primary packaging		EN 980 EN 1041	- Accord. to latest HELM Layout - Printing is clean, straight and legible
Colour		EN 980 EN 1041	Blue (Pantone 294C) and Black
Dimensions (LxW) [mm]		93mm x 152mm	

d. Secondary packaging

Name of component	Material	Method(s)	Specification and degree
Clinic Box	White board paper	EN ISO 11607	-
Layout secondary packaging		EN 980 EN 1041	According to latest HELM-Layout
Colour		EN 980 EN 1041	Blue (Pantone 294C) and Black
Dimensions (LxWxH) [mm]		250mmx160mmx108mm	
Weight		-	

e. Tertiary packaging

Name of component	Material	Method(s)	Specification and degree
Export Carton	Double Wall+ Kraft	EN ISO 11607	-
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]		560mm x 340mm x 290mm	

浙江润强医疗器械股份有限公司
ZHEJIANG RUNQIANG MEDICAL INSTRUMENTS CO., LTD.

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