



东利集团 (Dongli Group)

SD KANG LI LAI
Healthcare



Shuangli[®]

山东康利莱医疗器材有限公司

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山东康利莱医疗器材有限公司

SHANDONG KANGLILAI MEDICAL APPARATUS CO.,LTD.



企业简介 >>> COMPANY PROFILE

山东康利莱医疗器材有限公司于2008年5月经国家食品药品监督管理局产品注册、山东省食品药品监督管理局、山东省工商行政管理局批准成立的省级有限公司，注册资金3200万。

区位优势：公司位于国家重点黄蓝经济发展区内的昌邑市潍河岸边文山脚下，南望济青高铁、青银高速公路，北附荣乌高速，东接青岛，西连济南，成一小时经济工作圈，地理位置优越，交通发达便利。

基础设施：占地160亩，11000平方米符合GMP标准的十万级净化生产车间两座；3000平方米的科技研发中心楼一栋；2380平方米的职工餐厅一座，可容纳800人就餐；6000平方米的职工宿舍楼一栋，可供1000人居住；4000平方米的专家公寓一栋，可居住200人；拥有行业领先水平的生产设备180套，检测检验设备50余台。

人员结构：职工500余人，其中高级职称6名，中级专业技术人员12名，分别负责产品研发、生产管理、质量管控、采购营销、售后服务和其他职能岗位。

生产能力：开设注射车间、医用管路车间、口罩与医用防护服车间、成型车间、造粒车间、制水车间、制气车间。主要生产一次性使用输液器、一次性使用无菌注射器、一次性使用无菌溶药注射器、医疗防护用品和医用外科口罩及民用口罩、高压延长管等二、三类医疗器械产品。年产输液器7860万支，注射器558万支，各类医用导管产品300余万米。

口罩车间拥有全自动化生产设备25台，可日产一次性医用口罩和一次性使用医用外科口罩100-150万片。

销售网络：国内销售网络已覆盖山东省各地市，在上海、陕西、河北、吉林、辽宁、黑龙江、浙江、新疆等地建立了销售网点。与威高集团建立了友好的贸易往来。同时，积极开拓国际市场，产品销往俄罗斯、德国、韩国、塔吉克斯坦、印度、土耳其、意大利、尼日利亚、坦桑尼亚、伊朗、阿根廷、巴西、秘鲁、孟加拉等十几个亚欧非国家。

荣誉：潍坊市医疗器械质量管理先进单位，潍坊市诚信民营企业，潍坊市劳动保障诚信单位，潍坊市守合同重信用企业，潍坊市百佳民营服务企业，2010年“双利商标”被评为“山东省著名商标”。

未来：随着世界医药行业的蓬勃发展，医药产业在我国国民经济中比重的不断提高，我公司决心致力于开发高附加值的新型高精尖医疗器械产品，对现有产品进行改造升级，增加精密输液器、TPE输液器、避光输液器等高端医疗产品。同时携手国内有关科研机构对具有世界领先水平的心脏鞘管、心脏介入器材、脑引流器械进行攻关，使公司产品在同行业中处于领先地位。

Shandong Kanglilai Medical Apparatus Co., Ltd was established in May 2008 approved by SFDA, Shandong Food and Drug Administration and Shandong Administration for Industry and Commerce, registered capital of 32 million.

Location advantage: It is located in Changyi City, which is in the State Key Economic Development Circle of Yellow River – Blue Ocean, at the foot of Wenshan Hill on the bank of Weihe River and in the north of Jiqing Express Rail and Qingyin Expressway, in the south of Rongwu Expressway, Qingdao City closer to the east and Jinan City next to the west, an hour economic work circle has been formed. Superior geographical location, convenient transportation.

Infrastructure: It covers an area of 120,000 square meters , two purified workshops with 11,000 square meters meet the GMP standards of 100,000 class, 3,000 square meters of R & D Center, 2,380 square meters of worker canteen, 6000 square meters of worker dormitory building, 4000 square meters of staff apartment building. We have 180 sets of the advanced production facilities, more than 50 sets of testing and inspection equipment.

Human resources: more than 500 employees including 6 senior titles, 12 intermediate professional and technical personnel, respectively responsible for product research and development, production management, quality control, purchase and marketing, after-sales service and other function of positions.

Production capacity: There are workshop of syringes and infusion sets, medical pipeline workshop, workshop of face mask and medical protective clothing, molding workshop, granulation workshop, water purification workshop, steam production workshop. The main production of disposable infusion sets, disposable syringes, disposable dispensing syringe, medical protective clothing and face masks, high-pressure extension tube and others with class II & class III. The annual output of infusion set 78.6 million, syringe 5.58 million, all kinds of catheter products more than 3 million meters.

There are 25 fully automatic production equipment in the mask workshop, by which 1.5 million disposable medical masks and disposable medical surgical masks can be produced per day.

Sales network: the domestic sales network has covered all cities in Shandong Province, and has established sales outlets in Shanghai, Shanxi, Hebei, Jilin, Liaoning, Heilongjiang, Zhejiang and Xinjiang. Established friendly trade dealings with the Weigao Group. At the same time, actively opened up the international markets, most of the products have been sold to Russia, Germany, South Korea, Tajikistan, India, Turkey, Italy, Nigeria, Tanzania, Iran, Argentina, Brazil, Peru, Bangladesh and more than a dozen Asia-Europe-Africa countries.

Honours:

Weifang medical device quality management Outstanding enterprises

Weifang good faith private enterprise,

Weifang city labor security good faith enterprises ,

Weifang city abide by the contract good credit enterprise,

Weifang city hundred best private service enterprise ,

Shuangli trademark “ 2010 Shandong Province famous trademark ”.

National patent:

Sealing Detector for Medical drainage Bag

(Patent No. ZL 2013 2 0030149.5),

Stamping tooling for the solution filter into drip chamber

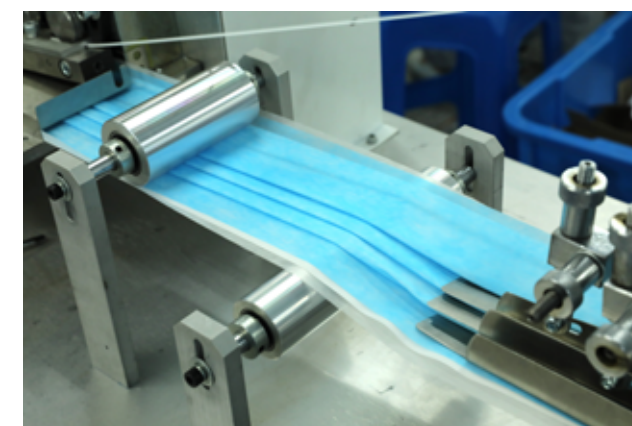
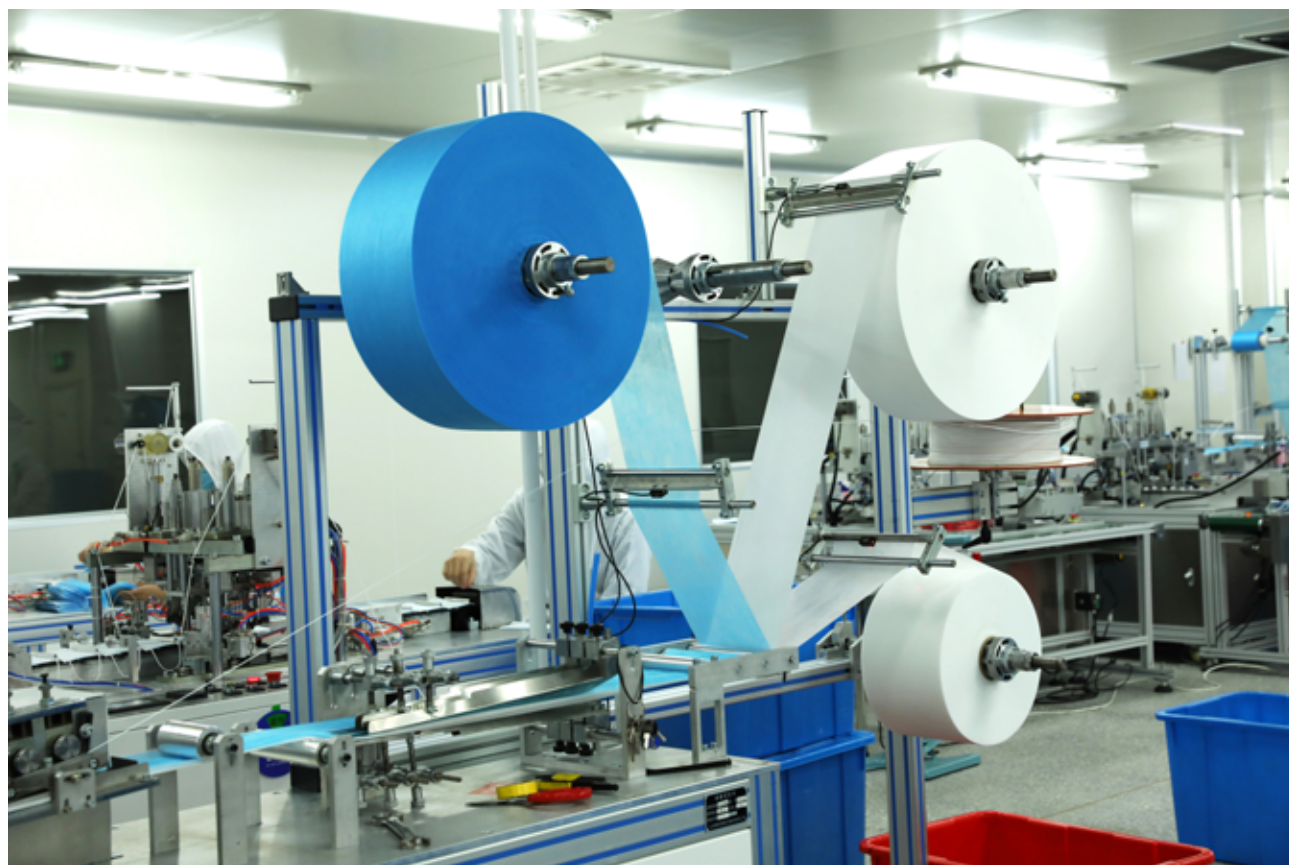
(Patent No. ZL 2013 2 0030077.4)

In the future:

with the vigorous development of the pharmaceutical industry in the world and the increasing proportion of the pharmaceutical industry in the national economy of our country, our company is determined to devote itself to the development of new high-precision medical device products with high added value, to upgrade the existing products, and to increase high-end medical products such as precision infusion set, TPE infusion set, light-proof infusion set and so on. At the same time, cooperation with domestic scientific research institutions to R & D heart sheath tube, heart intervention equipment and brain drainage apparatus.



■ 标准化设备 >>> ■ STANDARDIZED EQUIPMENT



■ 标准化设备 >>> ■ STANDARDIZED EQUIPMENT



质量控制 >>> QUALITY ASSURANCE SYSTEM

质量

1、坚持“以人为本，科技创新”原则，注重产品研发。“医用储液袋密封性检测仪”（专利号：ZL 2013 2 0030149.5）、“自动滴斗冲网机”（专利号：ZL 2013 2 0030077.4）获得国家专利。

2，坚信“产品的质量关系患者的生命，企业的质量管理关系企业的发展”理念，对产品的设计、原材料的采购、产品的生产组装、出厂检验、产品销售及售后服务等各个环节进行严密监控。同时，加强了化验室的工作，从原材料的入库、零部件的生产到成品的出库进行全程跟踪检验。产品出厂合格率达到100%。先后通过了EN ISO13485:2016质量体系认证、欧盟CE产品认证、GMP管理体系认证，其中一次性使用注射器带针、一次性使用输液器、一次性使用静脉注射针、一次性使用皮下注射针头、一次性使用输血器、尿袋、医用外科口罩等产品获得欧盟CE产品认证证书。

3、人才战略：公司质量负责人多次参与欧盟CE、美国FDA认证的相关知识培训，并在全公司举办相关知识讲座，培养大批全方位管控人才。完善的质量体系铸就完美的产品质量，严格的质量控制打造卓越的行业品牌。

Characteristics of quality controls:

1.Adhere to the principle of “People-oriented, scientific and technological innovation”. Focus on product development. Such as Sealing Detector for medical drainage bag with Patent No. ZL 2013 3 0030149.5 and Stamping tooling for solution filter in drip chamber with Patent No. ZL 2013 3 0030077.4

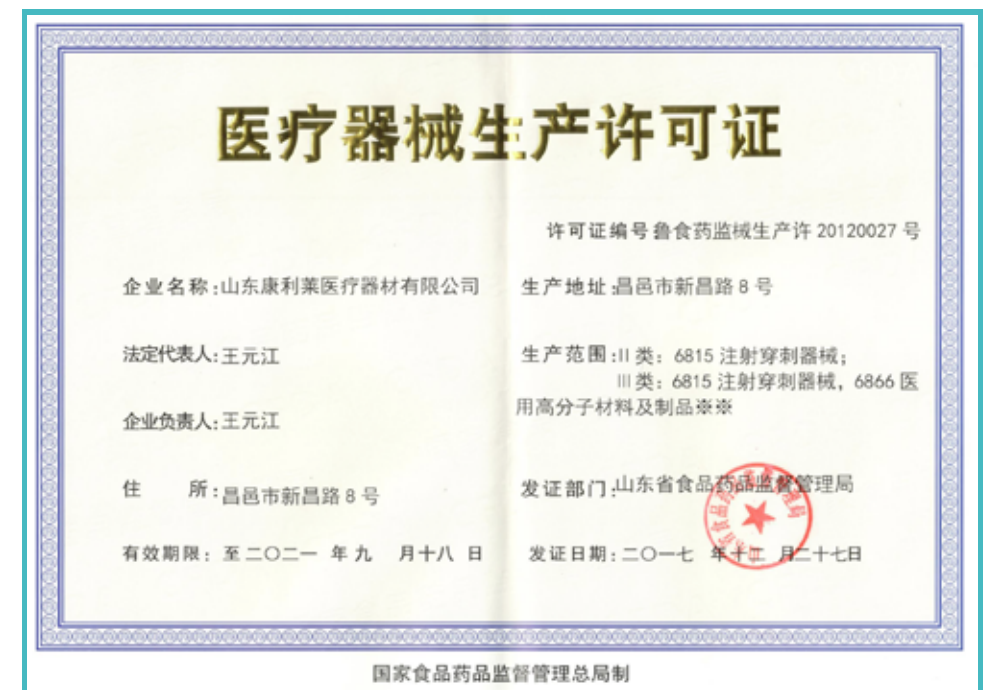
2.We firmly believe that "the quality of products related to the life of patients, quality management of enterprises related to the development of enterprise". Closly monitor all the aspects of the design of products, the purchase of raw materials, production procedure and assembly, factory inspection, product sales and after-sales service and other links .

At the same time, the working of laboratory has been strengthened in the whole process of tracking inspection from the storage of raw materials, parts production to finished products out of the warehouse. The qualified rate of the products has been 100%.

Successively obtained EN ISO13485: 2016 Quality System Authentication, the CE authentication issued by TUV Rheinland LGA Products GmbH, the GMP Management System Authentication. Disposable syringe with needle, disposable infusion set, disposable intravenous injection needle, Urine bag, medical mask, disposable blood transfusion set, disposable hypodermic needle and other products have been issued by CE 0197.

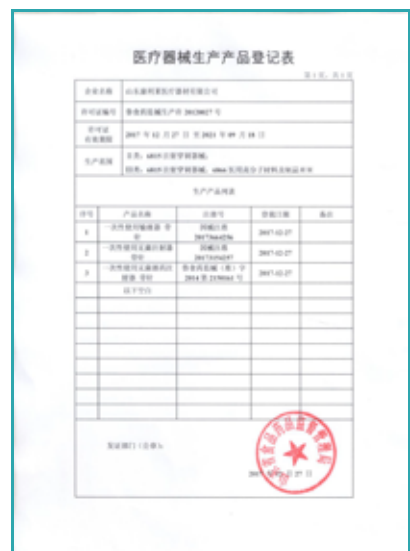
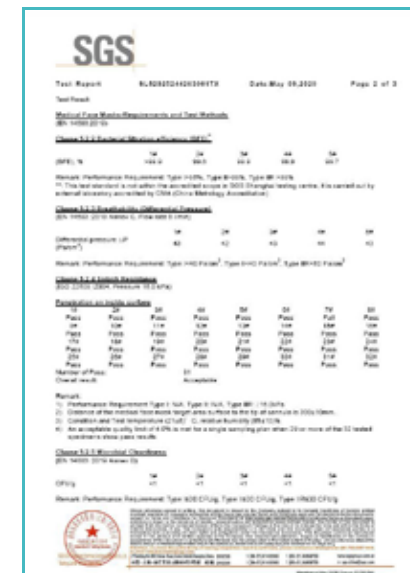
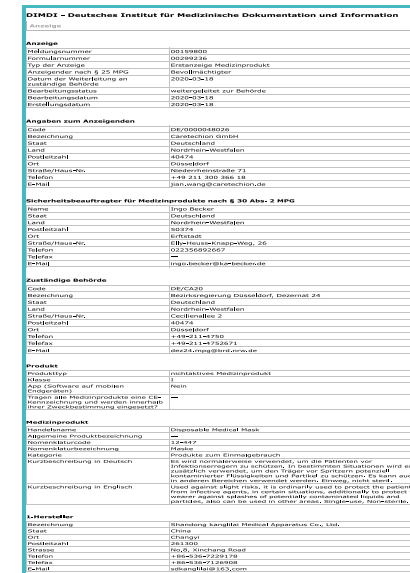
3.Talent Strategy: The quality staff took part in the relevant training of CE and FDA for many times. And held relevant knowledge lecture throughout our company to cultivate a large number of all-round management talents. Perfect quality system creates perfect product quality. And strict quality control creates excellent industry brand.

企业资质 >>> ENTERPRISE QUALIFICATION



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产品展示 >>> PRODUCT DISPLAY



隔离服



防护服



手术服



产品展示 >>>

PRODUCT DISPLAY

一次性医用口罩 Disposable Medical Mask

三层防护

three layers of protection

阻挡飞沫

preventing droplets

过滤病菌

filtering bacteria

三层防护 守护您的健康

外层：3S无纺布，有效隔离外界有害颗粒

中层：99熔喷布，高效过滤外界细微颗粒

底层：3S无纺布，防潮透气，柔软亲肤

EN 14683 Type I&II

国家商务部、药监局白名单



3Ply Protection

Leak Proof Non-woven Fabric(New Non-woven Fabric)
Effectively Inhibit And Isolate Harmful Particles And Gases
High Density Filter Layer(Fine Melt-blown Non-woven Fabric)
Great Efficient At Filtering Out Fine Particles
Direct Contact Skin Layer(New Non-woven Fabric)
Moisture-proof,breathable,non-toxic,non-stimulating,soft And Skin-friendly
EN 14683 Type I&II

产品展示 >>>

PRODUCT DISPLAY

医用外科口罩 Disposable Surgical Mask

三层防护

three layers of protection

阻挡飞沫

preventing droplets

过滤病菌

filtering bacteria

三层防护 守护您的健康

外层：3S无纺布，有效隔离外界有害颗粒

中层：99熔喷布，高效过滤外界细微颗粒

底层：3S无纺布，防潮透气，柔软亲肤

EN 14683 Type IIR

许可证编号：鲁食药监械生产许20120027号

注册号：鲁械注准20202140610



3Ply Protection

Leak Proof Non-woven Fabric(New Non-woven Fabric)
Effectively Inhibit And Isolate Harmful Particles And Gases
High Density Filter Layer(Fine Melt-blown Non-woven Fabric)
Great Efficient At Filtering Out Fine Particles
Direct Contact Skin Layer(New Non-woven Fabric)
Moisture-proof,breathable,non-toxic,non-stimulating,soft And Skin-friendly
EN 14683 Type IIR

产品展示 >>>

PRODUCT DISPLAY

输液器 Infusion set
OEM产品/ OEM products



IV-6-5LL-1



IV-6-5LL-2



IV-6-5LL-3

ITEM CODE:IV-6-5LL

Specfication:

20 drops vented spike with air vent

4.8cm drip chamber with 12.8mm 15µm filter

ABS roller clamp

Latex or latex-free bulb or Y injection site

Luer lock connector (PP or ABS or PVC)

Luer cap(PE) or with needle

Available tubing:Transparent,Translucent

Available material:PVC,DEHP-FREE,Light-proof

Available package:PE Pouch,PE/dialyzing paper,Blister package



IV-6-5S-1



IV-6-5S-2



IV-6-5S-3

ITEM CODE:IV-6-5S

Specfication:

20 drops vented spike with air vent

4.8cm drip chamber with 12.8mm 15µm filter

ABS roller clamp

Latex or latex-free bulb or Y injection site

Luer slip connector (PP or ABS)

Cap or with needle

Available tubing:Transparent,Translucent

Available material:PVC,DEHP-FREE,Light-proof

Available package:PE Pouch,PE/dialyzing paper,Blister package

产品展示 >>>

PRODUCT DISPLAY

输液器 Infusion set
OEM产品/ OEM products



IV-6-1-A



IV-6-1-B



IV-6-1-C

ITEM CODE:IV-6-1

Specfication:

20 drops vented spike with air vent

6.2cm drip chamber with 14.2mm 15µm filter

ABS roller clamp

Latex or latex-free bulb or Y injection site

Luer lock connector (PP or ABS or PVC)

Luer cap(PE) or with needle

Available tubing:Transparent,Translucent

Available material:PVC,DEHP-FREE,Light-proof

Available package:PE Pouch,PE/dialyzing paper,Blister package



IV-5-3C

20 drops vented spike with air vent with wings

6.4cm drip chamber with 14.2mm 15µm filter

ABS roller clamp

Latex or latex-free bulb or Y injection site

Luer lock connector (PP or ABS or PVC)

Luer cap(PE) or with needle

Available tubing:Transparent,Translucent

Available material:PVC,DEHP-FREE,Light-proof

Available package:PE Pouch,PE/dialyzing paper,Blister package



IV-5-3

20 drops vented spike with air vent with wings

5.2cm drip chamber with 13.2mm 15µm filter(or without)

ABS roller clamp

Latex or latex-free bulb or Y injection site

Luer lock connector (PP or ABS or PVC)

Luer cap(PE) or with needle

Available tubing:Transparent,Translucent

Available material:PVC,DEHP-FREE,Light-proof

Available package:PE Pouch,PE/dialyzing paper,Blister package

产品展示 >>>

PRODUCT DISPLAY

输液器/注射器/输血器 Infusion set/Syringe/Blood transfusion set
OEM产品/ OEM products



IV-6-5F/IV-6-1F/IV-5-3F

20 drops vented spike with air vent
4.8cm or 6.2 cm or 5.2cm drip chamber with filter
Pinch clamp and precision regulator
Latex or latex-free bulb or Y injection site
Luer lock connector (PP or ABS or PVC)
Luer cap(PE)
Available tubing: Transparent, Translucent
Available material: PVC, DEHP-FREE, Light-proof
Available package: PE Pouch, PE/dialyzing paper, Blister package



IV-6-6

spike without air vent
4.8cm drip chamber with or without 12.8mm 15µm filter
ABS roller clamp
With or without bulb or Y injection site
Luer lock or Luer slip connector
Luer cap or with needle
Available tubing: Transparent, Translucent
Available material: PVC, DEHP-FREE, Light-proof
Available package: PE Pouch, PE/dialyzing paper, Blister package



Disposable Syringe

Syringe with Luer slip or luer lock connector
1ml, 2.5ml, 5ml, 10ml, 20ml, 50ml
Transparent
Latex or Latex free
with needle
EO Sterilization
Available package: PE Pouch, Blister package



Blood transfusion set

spike with or without air vent
9.2cm drip chamber with 62mm 17.3µm filter
ABS roller clamp
Latex or latex-free bulb or Y injection site
Luer lock or luer slip connector
Luer cap or with needle
Available tubing: Transparent
Available material: PVC
Available package: PE Pouch, PE/dialyzing paper, Blister package

产品展示 >>>

PRODUCT DISPLAY

配件 Parts
OEM产品/ OEM products



scalp vein set



Roller clamp



bulb



needles



Drip Chamber



connector

产品展示 >>>

Infusion Set



Item Code: IV-5-3-2

Specification: Air vented spike with cap
62mm drip chamber with solution filter
20 or 60 drops=1ml
Roller Clamp Tubing
Luer lock connector with cap

Available material: PVC, DEHP Free PVC, PVC Free

Available package: Blister package, PE pouch

Reference standard: ISO8536-4

产品展示 >>>

Infusion Set /Blood Transfusion Set



Item Code: IV-5-3-4

Specification: Air vented spike with cap
72mm drip chamber with solution filter
20 or 60 drops=1ml
Roller Clamp Tubing Y-injection port
Luer lock connector with cap

Available material: PVC, DEHP Free PVC

Available package: Blister package, PE pouch

Reference standard: ISO8536-4

Item Code: IV-5-3-3

Specification: Air vented spike with cap
62mm drip chamber with solution filter
20 or 60 drops=1ml
Roller Clamp Tubing

Luer lock connector with air filter eliminator cap

Available material: PVC, DEHP Free PVC,PVC Free

Available package: Blister package, PE pouch

Reference standard: ISO8536-4



Item Code: BT-3-D

Specification: Spike with cap
Double drip chamber with filter
Roller Clamp Tubing
Latex free flashbulb
Luer lock connector with cap

Available material: PVC, DEHP Free PVC

Available package: Blister package, PE pouch

Reference standard: ISO1135-4



Item Code: IV-5-3-D

Specification: Air vented spike with cap
Double drip chamber 20 or 60 drops=1ml
Roller Clamp Tubing
Luer lock connector with cap

Available material: PVC, DEHP Free PVC,PVC Free

Available package: Blister package, PE pouch

Reference standard: ISO8536-4



Item Code: BT-3-2

Specification: Spike with cap
Drip chamber with filter
Roller Clamp Tubing
Latex free flashbulb
Luer lock connector with cap

Available material: PVC, DEHP Free PVC

Available package: Blister package, PE pouch

Reference standard: ISO1135-4

产品展示 >>>

Burette



Specification: 100ml
 60 drops =1ml
Available material: PVC, DEHP Free
Available package: in bulk
Reference standard: ISO8 536-5



Specification: 150ml
 60 drops =1ml
Available material: PVC, DEHP Free
Available package: in bulk
Reference standard: ISO8536-5



Two-way connector
Material: PVC
For the tube OD:
 2.5mm or 4.1mm



Three-way connectors
Material: PVC
For the tube OD:
 2.5mm or 4.1mm



Luer slip connectors with check valves
Material: ABS
For the tube OD: 4.1mm

产品展示 >>>

connectors



Male luer lock connector with cap
Material: ABS
For the tube OD: 4.1mm



Male luer lock connector with cap
Material: ABS
 For connecting the flashbulb



Female luer lock connector with cap
Material: ABS
For the tube OD:
 2.5mm or 4.1mm



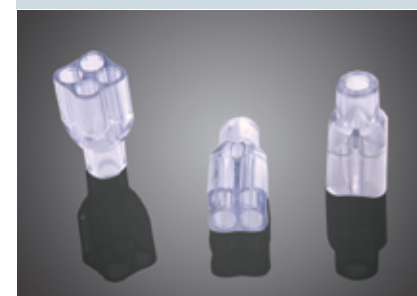
Male luer lock connector with cap
Material: ABS
For the tube OD:
 2.5mm or 4.1mm



Rotating male luer lock connector with cap
Material: ABS
For the tube OD: 4.1mm



Rotating male luer lock connector with cap
Material: ABS
For the tube OD: 4.1mm



Four-way connectors
Material: PVC
For the tube OD: 4.1mm



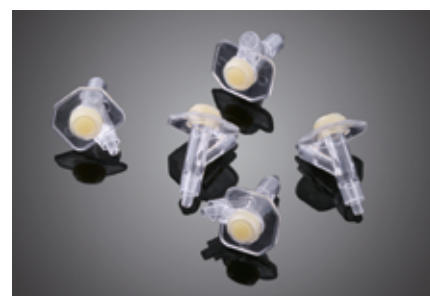
Four-way connectors
Material: PVC
For the tube OD: 2.5mm



Four-way connectors
Material: PVC
For the tube OD: 7.8mm

产品展示 >>>

Drip Chamber



"Y" injection site without finger protector
Material: ABS
For the tube OD: 4.1mm



Specification:
 Air vented spike with cap,
 drip chamber with
 filter inside,
 20 drops=1ml



Specification:
 Air vented spike with cap,
 drip chamber with
 filter inside,
 60 drops=1ml



Specification:
 Air vented spike with cap,
 drip chamber with
 filter inside,
 20 or 60 drops=1ml



Specification:
 Spike with cap,
 drip chamber with
 filter inside,
 20 drops=1ml



Specification:
 Spike with cap,
 drip chamber with
 filter inside,
 60 drops=1ml

产品展示 >>>

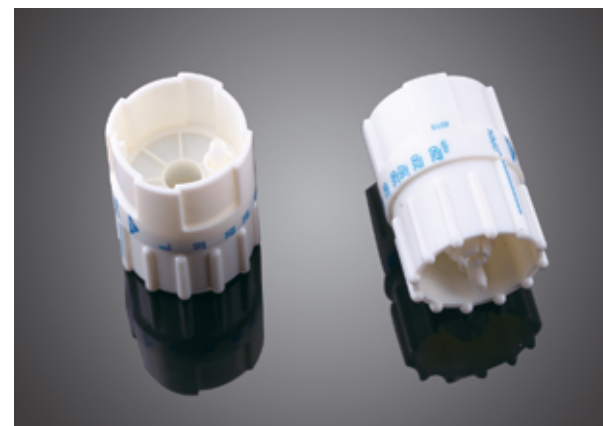
Clamps



Material: ABS
Available color:
 White, orange or blue



Material: ABS
Available color:
 White, orange or blue



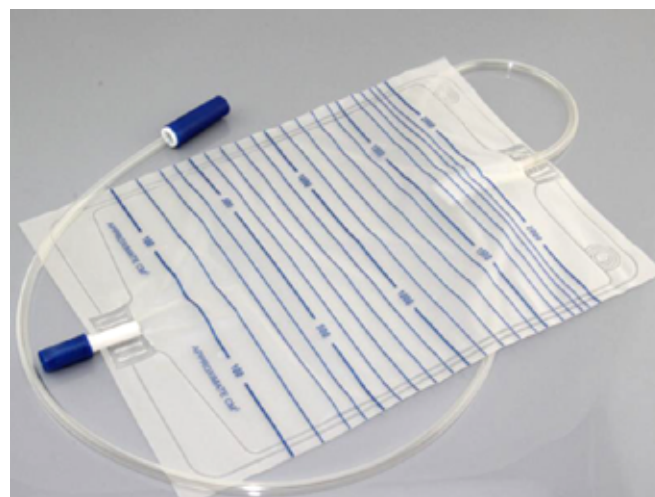
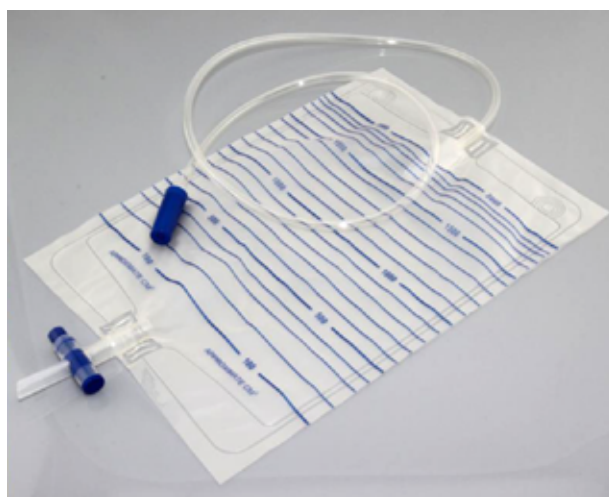
Precise flow regulator
Material: ABS
For the tube OD: 4.1mm



Precise flow regulator
Material: ABS
For the tube OD: 4.1mm

产品展示 >>>

Urine Bag



Stopcock



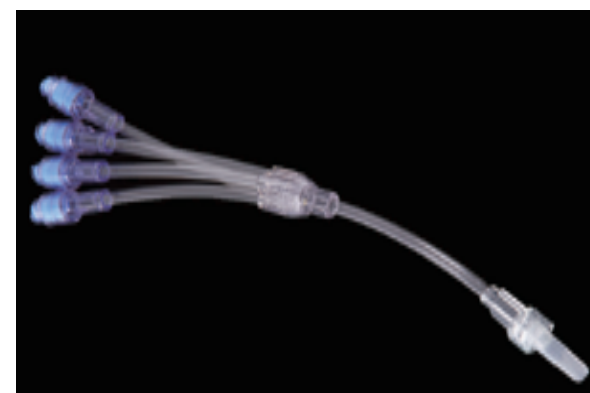
Three-way stopcock
Material:ABS
For the tube OD:4.1mm



Three-way stopcock
Material:ABS

产品展示 >>>

Multi-way Needleless extension line



Specification:
With four-way needleless
injection port
Available material:
PVC,DEHP Free
Available material:
Blister package,PE pouch
For the tube OD 2.5mm or 4.1mm



Specification:
With two-way needleless
injection port
Available material:
PVC,DEHP Free
Available material:
Blister package,PE pouch
For the tube OD 4.1mm

High pressure extension tube



提供各种精密医用管路及其他特种挤出。管路产品，材质、尺寸及形状按客户要求定做，可生产PU.PA.PE.APC.PP.PVC.PEBAX.POM.ABS等材质，外径介于0.3mm到20mm之间的导管，尺寸公差控制在 $\pm 0.02\text{mm}$ 之间。亦可提供OEM各类产品代加工。
Various kinds medical precision catheters and other special tubes can be provided by Kanglilai. And we can produce catheters and tubes in accordance of technical requirements by sellers on materials,sizes and appliances.Various kinds of catheters and tubes can be made of PU,PA,PE,PP,PVC,PEBAX,POM,ABS tec.The range of outer diameter is at 0.3mm--20mm and dimension tolerance is $\pm 0.02\text{mm}$,Also provide catheters and tubes with OEM.