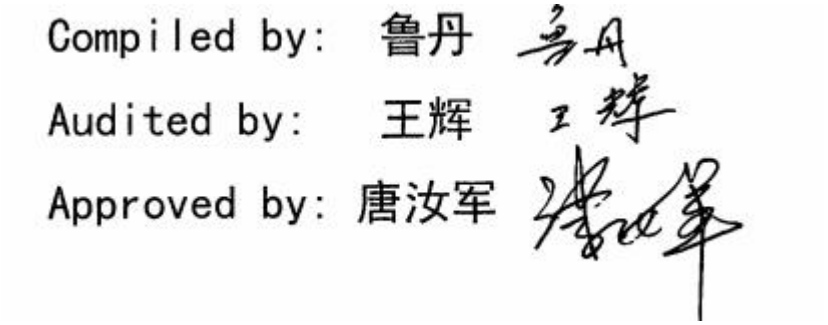
CE technical files:
I.V.Catheter



Date: 20230726

JIANGSU KANGBAO MEDICAL EQUIPMENT CO., LTD.
78#, North Suzhong Road, Baoying, Yangzhou, Jiangsu Province, P. R. China

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	0B: Content	Date: 20230726
		Revision: 04

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	01: Manufacturer information	Date: 20230726
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Overview of company

We-JIANGSU KANGBAO MEDICAL EQUIPMENT CO., LTD. oration is a professionalization factory engaged in manufacturing various disposable medical products, and is a professionalization out-going factory for export.

There are 340 staffs in the company now, in which four engineers. We have Technical department, production department, quality department, sales and purchase department, human resource department, etc.

We have built a 100000 class clean room about 10000 ㎡.The process is reasonable; technology is advanced 、 automatic 、 convenient 、 and with stable performance. JIANGSU KANGBAO MEDICAL EQUIPMENT CO., LTD. oration offers a wide range of medical disposable products. The main disposable medical products are all type I.V.C, Infusion connector (Heparin cap, needle free connector),3-way stopcock(with or without extension tube),etc. JIANGSU KANGBAO MEDICAL EQUIPMENT CO., LTD. oration also undertakes OEM products.

Stringent adherence to total quality management principles are maintained as well as the standards of Good Manufacturing Practice from product design criteria to the finished products and after sales service. JIANGSU KANGBAO MEDICAL EQUIPMENT CO., LTD. oration's quality system is certified by TUV in conformity to EN ISO 13485:2016 standards. All products manufactured by JIANGSU KANGBAO MEDICAL EQUIPMENT CO., LTD. oration are CE marked.

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	02: Approval sheet	Date: 20230726
		Revision: 04

PREPARED BY	SIGNATURE
QM Administrative representative（Technical CEO） Mr.Luhui	
Production Director Mr: Tangrujun	
QC Manager Miss:LUdan	
Head of Technique Department Mr:Wanghui	
Workshop Director Mr.Zhuwanxi	
Physical checker Miss Zhuyuxie	
Chemical checker Miss Yujingjing	
Biological checker Miss Zhuyuxie	
Date	

JIANGSU KANGBAO MEDICAL EQUIPMENT CO., LTD.	CE technical file I.V.Catheter	Page: 01-01
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	03: I.V.C catalogue	Date: 20230726
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I.V. Catheter
I.V.C ---Pen –like (without wings, without injection port)
I.V.C--- With injection port & wings
I.V.C----With wings without injection port
I.V.C----Y-type
Safety I.V. Catheter
I.V.C.S--Pen –like (without wings, without injection port)
I.V.C.S--With injection port & wings
I.V.C.S--With wings without injection port

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	04 Technical parameter and instruction	Date: 20230726
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一、Technical details:

- ◆ Backout needle bevel for easier, less atraumatic insertion
- ◆ Thin wall FEP(PU)catheter with 3 or more embedded X-Ray contrast lines provides high flow rate
- ◆ Flexible and kink resistant catheter is double tapered with a rounded tip for smooth introduction and minimal discomfort to the patient.
- ◆ Flexible wings provide easy and secure fixation and also prevent skin contact with luer lock connection

  Hydrophobic blood stopper ◆Color coded ◆Luer lock（6：100） fitting.
- ◆ Sterilized by E.O.

Standard color and basic data of I.V. Catheter

Gauge	Color Code	Catheter Parameter (mm)				Flow Rate (ml/min)
		Nominal O.D	I.D	O.D	Effective Length	
14 G	Orange	1.9,2.0,2.1,2.2	1.45-1.70	1.75-2.0	45/51±2	3000--210
16 G	Grey	1.6 , 1.7 , 1.8	1.25-1.30	1.50-1.60	45/51±2	188--148
17 G	White	1.4 , 1.5	1.10-1.15	1.35-1.4	45/51±2	130-110
18 G	Deep Green	1.2 , 1.3	1.00-1.05	1.20-1.25	32 / 45±2	98--84
20 G	Pink	1.0 , 1.1	0.75-0.84	1.00-1.07	25 / 32±2	70--55
22 G	Deep Blue	0.8, 0.9	0.60-0.65	0.80-0.90	19 / 25±1.5	47-37
24 G	Yellow	0.7	0.50-0.55	0.74	19±1.5	28
26 G	Violet	0.6	0.45	0.64	19±1.5	20

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INSTRUCTIONS FOR USE

Intravascular Catheter Over needle Peripheral Catheter (I.V.Catheter)

Version：B0

1 Material:

FEP/TPU, PE, PP, ABS, Stainless Steel.

2 Applications specification

Creation of secure peripheral venous access.

Including 16G,18G,20G,22G,24G。

3 Indications

Blood transfusions or infusion of I.V solutions suitable for administration via peripheral veins. Intermittent intravenous drug administration. Prophylactic creation of a secure venous access in

Patients who may require urgent intravenous drug administration, in particular prior to diagnostic or therapeutic procedures.

Safety I.V.C should be retraction to the bins when remove the needle, and the needle cannot be push or pull after the needle retraction, and cannot be recycle again, this function not only can avoid injury to the human, but also to avoid the contamination to the blood of patient and nurse.

4 Contraindications

The catheter should not be used in patients with known hypersensitivity to any of the materials employed.

5 Risks

Depending on how long the catheter is left in situ on the type and amount of infusions or injections administered, and on individual predisposition,thrombophlebitis may occur in the accessed vein.

Reused will bring cross-infection.

6 Duration of use

No maximum duration can be given. Normal use, it can be used kept in the vein for less than 48hours for single use and its accumulative usage time shall be less than 30 days.

Consider the use of the characteristics of the product, the cumulative time may be exceed 30 days, the puncture site should be checked at regular intervals, and it should be removed in the event of local or systemic signs of infection.

7 Warning

After withdrawal, do not reintroduce the steel Cannula into the catheter as the latter may be cut off, leading to catheter embolism. Use only if packaging is intact.

8 Storage

Until needed, the products should be stored in its original packaging at temperatures between 10 and 25 and at 50% to 60% humidity. Protect from direct light exposure. If stored properly, the product may be used up to the expiry date printed on the packaging.

9 Uses

A Remove protective cap after disinfection of puncture site.

B Puncture chosen vein. Grip plate technique avoids contamination of luer lock-hub. Success of puncture is visible due to flash-back of blood within capillary as well as within the region of the blood flash-back chamber.

C Advance catheter into vein and simultaneously withdraw steel needle.Attention:Do not re-insert steel needle into catheter because of danger of shearing the catheter and thus causing catheter embolism.

D Perform wings or catheter hub according to anatomical necessity of puncturing site. Turn down wing whilst or catheter hub holding cannula in place. In order to avoid contamination the

lock hub should not be touched.

E Fix wings or catheter hub to skin with adhesive dressing .The steel needle remains in situ to avoid

Bleeding as well as to stabilize catheter during fixation.

F Withdraw steel needle completely while pressing vein just beyond the tip of the catheter. Connect the I.V.line.For additional safeties choose lock connection.

G Cover puncturing site with sterile dressings.

H For short-term interruption of I.V.administration use sterile stopper Combi-red.A heparinized normal saline solution avoids blood coagulation.

I For long-term interruption of I.V.administration introduce sterile mandarin (stylet).To avoid risk of any blood escaping,press vein just beyond the tip of the catheter.

J Repeated blood sampling for analysis purpose can be performed with the yellow In-stopper.The Latex membrane allows for multiple withdrawals and intermittend injections. Flush it afterwards with normal saline.Disinfect the In-stopper prior to renew sampling.

K Strip wings or catheter hub ensures optimal fixation (immobilization)of catheter .Kinking of catheter as well as vein wall irritations are being avoided.

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05 Raw materials

Part of product	Material	Remark
Catheter hub	PP	Medical Grade
Needle hub	PC	Medical Grade
Injection port	PP	Medical Grade
Catheter Protective tube	PE	Medical Grade
Needle	SUS304	For Medical Use
Stainless clips	SUS304	For Medical Use
Screw cap	PP(ABS)	Medical Grade
Exhaust site	PE	Medical Grade
Harzard blister	PVC	Medical Grade
Packing Paper	PAPER	For Medical Use
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JIANGSU KANGBAO MEDICAL EQUIPMENT CO., LTD.	CE technical file I.V.Catheter	Page: 01-01
		File No: PL-IVC-TF-A
	06 Environment control	Date: 20230726
		Revision: 04

Production and assembling of accessories and components of I.V. CANNULA for single use are completed in 100000 grade cleanliness workshop.
Control requirements of 100000 grade cleanliness workshop:

Monitoring items		Technical guideline	Accordance	Check Frequency
Temperature, ℃		18～28	JGJ-1990	1 time/shift
RH, %		45～65	JGJ-1990	1 time/shift
Aeration frequency, time(s)/hour		≥15	JGJ-1990	1 time/month
Wind speed, m/s		——	JGJ-1990	1 time/month
Static pressure difference, Pa		≥5 between different grade cleanliness room (area) and between cleanliness room (area)and non-cleanliness room (area)	JGJ-1990	1 time/month
		≥10 between cleanliness (area) and outdoor air		
Dust particles, particle(s)/m^3	≥0.5μm	≤3500000	GB/T1629	1 time/quarter
	≥5μm	≤2000		
Float bacterium, cfu/ m^3		500	GB/T16293	1 time/quarter
Sedimentary bacterium, cfu/dish		≤10	GB/T16293	1 time/week

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JIANGSU KANGBAO MEDICAL EQUIPMENT CO., LTD.	CE technical file I.V.Catheter	Page: 01-01
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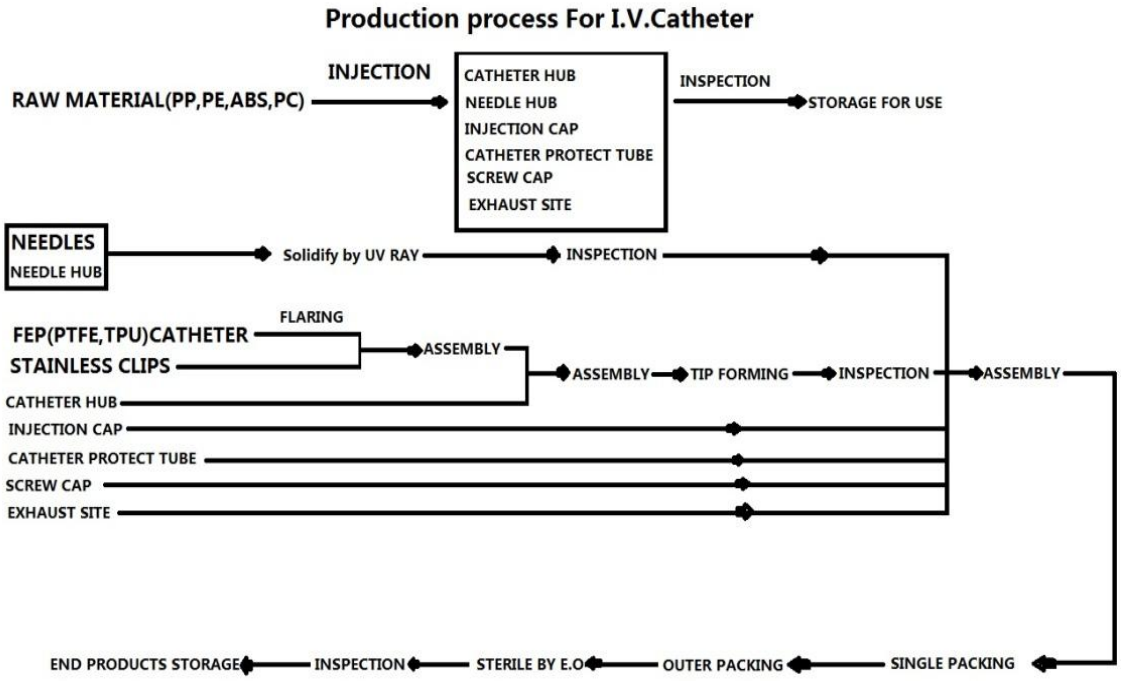
	07 manufacture procedure	Date: 20230726
		Revision: 04



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JIANGSU KANGBAO MEDICAL EQUIPMENT CO., LTD.	CE technical file I.V.Catheter	Page: 01-01
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	08 packing control	Date: 20230726
		Revision: 04

09 Single Packing Control

Parameter setting table of Blister packing machine

Equipment number	Blister packing machine		Equipment number	DPB-250E-010		
Parameter	Speed of frequency conversion	Temperature of up - mould （^{O}C）	Temperature of down-mould （^{O}C）	Temperature of heat sealing for up-mould （^{O}C）	Working pressure （Mpa）	Time of heat sealing （S）
Parameter setting	40-50	100±5	100±5	115±5	0.5±0.1	1.5±0.5

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JIANGSU KANGBAO MEDICAL EQUIPMENT CO., LTD.	CE technical file I.V.Catheter	Page: 01-01
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	09 sterile controls	Date: 20230726
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Sterilization parameter	
Sterilization temperature	50±3℃
Keep temperature time	60MIN
Pre-temperature	50±3℃
Keep pressure time	5MIN
pressure	-22Kpa---10Kpa
Humidity	30--85％
EO does, density	600MG/L
Sterilization time	480min
Exchange air vacuum	2.0KPa±0.1KPa
Exchange air times & time	3TIMES,15MIN

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Risk Management Report

Company Name:	江苏康宝医疗器械有限公司 JIANGSU KANGBAO MEDICAL EQUIPMENT CO., LTD.
Company Address:	江苏省扬州市宝应县苏中北路 78 号 78#, North Suzhong Road, Baoying, Yangzhou, Jiangsu Province, P. R. China
Product:	一次性使用静脉留置针 I.V. Catheter
Model:	加药型（14G—26G）、笔杆型（14G—26G）、蝴蝶型（14G—26G）
Accessories:	N/A
Standard:	EN ISO 14971:2019
Result:	All risks associated with the identified hazards have been evaluated. After appropriate measures to reduce these risks have been taken, the overall level of risk of the product is acceptable with regard to the intended application and use of the application.

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JIANGSU KANGBAO MEDICAL EQUIPMENT CO., LTD.	CE technical file I.V.Catheter	Page: 03-02
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	11 Risk Management Report	Date: 20230726
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Identification of qualitative and quantitative characteristics (acc. to EN ISO 14971:2012, cl. 4.2)

1	Intended use and how to use	I.V. Cannula for single use on clinical can prevent crosseinfcition by intravenous injection of medicine nutritious liquid.
2	Intended to be implanted	N
3	Intended to contact with patient or other persons	Y
4	Materials/components utilized/used/in contact with	Catheter、needle
5	Energy to/from patient	N
6	Substances to /from patient	N
7	Biological materials processed	N
8	Sterile/Intended to be sterilized, other microbiological control applicable	Sterilized by, products of no bacterium, no pyrognicity
9	routinely cleaned and disinfected by the user	N
10	Modify patient environment	N
11	Are measurements taken	N
12	Interpretative	N
13	use in conjunction with medicines or other medical technologies	Y
14	Unwanted outputs of energy or substances	Y
15	Susceptible to environmental influences	N
16	influence the environment	Y
17	Consumables/accessories associated	N
18	Routine maintenance/calibration	N
19	Software	N
20	Restricted “shelf-life”:	Y, 5 years
21	Delayed and/or long-term use effect	Y
22	Mechanical forces	N
23	Lifetime of the device determined	Sterilization validity ,Aging
24	Single use/re-use	Y,Single use
25	safe decommissioning or disposal	Y

26	Special training required to install or use	Y,only those skilled doctors with specialized training can use it
27	Information for safe use	Y, mark and specifications
28	new manufacturing processes need to be established or introduced	N
29.1	successful application of the medical device critically dependent on human factors, such as user interface	N
29.2	Can the user interface design features contribute to use error	N
29.3	Used in an environment where distractions can cause use error	N
29.4	Connecting parts or accessories	N
29.5	Control interface	N
29.6	Display information	N
29.7	Controlled by a menu	N
29.8	Used by persons with special needs	N
30	User interface be used to initiate user actions	N
31	Use an alarm system	N
32	Deliberately misused	N
33	Hold data critical to patient care	N
34	Intended to be mobile or portable	Y
35	Use of the medical device depend on essential performance	N

No.	Hazard		Risk Evaluation				Risk Reduction Measure	Evidence	NH	ALOR
	General	Identify hazards	S	O	D	RL				
D2. Energy Hazards										
1	电能 Electricity	NA	0	0	0	0	None			
2	热 Heat	NA	0	0	0	0	None			
3	机械力 Mechanical force	NA	0	0	0	0	None			
4	离子辐射 Ionizing radiation	NA	0	0	0	0	None			
5	非离子辐射 Non-ionizing radiation	NA	0	0	0	0	None			
6	电磁场 Electromagnetic fields	NA	0	0	0	0	None			
7	可移动部件 Moving parts	NA	0	0	0	0	None			
8	悬浮物 Suspended masses	NA	0	0	0	0	None			
9	支持病人器械失败 Patient support device failure	NA	0	0	0	0	None			
10	压力(管壁破裂) Pressure(vessel rupture)	NA	0	0	0	0	None			
11	声压 Acoustic pressure	NA	0	0	0	0	None			
12	振动 Vibration	NA	0	0	0	0	None			
13	磁场 Magnetic fields(e.g. MRI)	NA	0	0	0	0	None			
D3. Biological hazards 生物危害										
1	微生物污染 Bio-contamination	在生产过程中，袋体表面发生污染 Bag ship will be contaminated in the surface while manufacturing	3	3	3	27	控制产品初始污染、环境人员控制、灭菌控制、人员控制 Control of the products' initial pollution, ambient staff, sterilization staff	有关测试结果证明 Related test result evidence	No	Yes
2	生物不相容 Bio-incompatibility	袋体材料与人体不相容 The material of the bay is not compatible with the human body.	3	2	3	18	控制材料 Control material	有关测试结果证明 Related test result evidence	No	Yes
3	不正确的成份(化学组成) Incorrect formulation(chemical		0	0	0	0	None		No	Yes

No.	Hazard		Risk Evaluation				Risk Reduction Measure	Evidence	NH	ALOR
	General	Identify hazards	S	O	D	RL				
	composition)									
4	毒性 Toxicity	产品、袋体沉积物使使用者感染 Products、the deposit of bay ship will cause infection.	2	2	2	8	控制材料应是无毒材料 Contra material should be no poisonous matterid	有关材料标准和测试结果证明 Related material standards and test result evidence	No	Yes
5	变态反应性 allergenicity	NA	0	0	0	0	None		No	Yes
6	诱变性 mutagenicity	NA	0	0	0	0	None		No	Yes
7	致瘤性 oncogenicity	NA	0	0	0	0	None		No	Yes
8	致畸性 teratogenicity	NA	0	0	0	0	None		No	Yes
9	致癌性 Carcinogenicity	NA	0	0	0	0	None		No	Yes
10	再感染，交叉感染 Re-and/or cross-infection	双重污染 Dual-pollution	2	2	2	8	控制无毒材料不重复使用 Contrid no poisonous' no-re-use	有关材料标准和测试结果证明 Related material standards and test result evidence	No	Yes
11	致热性 pyrogenicity	NA	0	0	0	0	None		No	Yes
12	不能保持卫生安全 Inability to maintain hygienic safety	车间环境不达标，人员卫生不符合标准 The enviroment of workshop is under standards, staff's health is not suit for standards.	3	3	3	27	控制产品灭菌过程 Control of the process of sterilizing products	灭菌记录和无菌检测结果证明 The record of sterilization and test result evidence.	No	Yes
13	降解 Degradation	NA	0	0	0	0	None		No	Yes
D4. Environmental hazards and contributory factors 环境危害及其形成因素										
1	电磁场	NA	0	0	0	0	None		No	Yes

No.	Hazard		Risk Evaluation				Risk Reduction Measure	Evidence	NH	ALOR
	General	Identify hazards	S	O	D	RL				
	electromagnetic fields									
2	不充足的能量或冷却提供 Inadequate supply of power or coolant	NA	0	0	0	0	None		No	Yes
3	对电磁干扰的敏感性 Susceptibility to electromagnetic interference	NA	0	0	0	0	None		No	Yes
4	电磁干扰的发射 Emissions of electromagnetic interference	NA	0	0	0	0	None		No	Yes
5	不充足的能量提供 Inadequate supply of power	NA	0	0	0	0	None		No	Yes
6	不充足的冷却提供 inadequate supply of coolant	NA	0	0	0	0	None		No	Yes
7	储存或操作偏离规定的外部环境条件 Storage or operation outside prescribed environmental conditions	NA	0	0	0	0	None		No	Yes
8	与其它器械不相容 Incompatibility with other devices	NA	0	0	0	0	None		No	Yes
9	意外的机械危害 Accidental mechanical damage	NA	0	0	0	0	None		No	Yes
10	废弃物和/或器械处置的污染 Contamination due to waste products and /or device disposal	包装、标签、使用说明不全面、准确 Package, label, unoverall and inaccurate of the use of direction	1	1	1	1	完善标签、使用说明 Better lab and use of direction	包装标签、使用说明 Package label and use of direction	No	Yes
D5. Hazards resulting from incorrect output of energy and substances 不正确的能量和物质输出产生的危害										
1	电能 electricity	NA	0	0	0	0	None		No	Yes

No.	Hazard		Risk Evaluation				Risk Reduction Measure	Evidence	NH	ALOR
	General	Identify hazards	S	O	D	RL				
2	辐射 radiation	NA	0	0	0	0	None		No	Yes
3	音量 volume	NA	0	0	0	0	None		No	Yes
4	压力 pressure	NA	0	0	0	0	None		No	Yes
5	医疗气体的供应 supply of medical gases	NA	0	0	0	0	None		No	Yes
6	麻醉剂的供应 supply of anaesthetic agents	NA	0	0	0	0	None		No	Yes
D6. Hazards related to the use of the device and contributory factors 使用器械危害及其形成因素										
1	不适当的标签 Inadequate labeling	不足够信息使使用者发生伤害 Inadequate information causes the user's harm.	2	2	2	8	完善产品包装文件 Battement of the products package file	标签和语言信息使用说明 Label and information language's use of direction	No	Yes
2	不适当的使用手册 Inadequate operating instructions 如： ▪ 附件技术规范不适当 inadequate specification of accessories ▪ 预使用检查规范不适当 inadequate specification of pre-use checks ▪ 操作说明书过于复杂 over-complicated operating instructions ▪ 服务和维修规范不适当 inadequate specification of service and maintenance	不足够信息使使用者发生伤害 Inadequate information causes the user's harm. 检测不充分 Inadequate of measurement	2 0 2 0 0	2 0 2 0 0	2 0 2 0 0	8 0 8 0 0	完善产品包装文件 Battement of the products package file None 编制操作指导书依照标准 Edite operation direction by standards None None	标签和语言信息使用说明 Label and information language's use of direction 标准作业指导书 Standard work direction book	No No No No No	Yes Yes Yes Yes Yes
3	由无经验或未经培训的人使用 Use by unskilled/untrained	使用人员未培训 No training	3	3	3	27	人员培训 Training the staff	资格证明 Qualification evidence	No	Yes

No.	Hazard		Risk Evaluation				Risk Reduction Measure	Evidence	NH	ALOR
	General	Identify hazards	S	O	D	RL				
	personnel	of the work staff								
4	合理的可预见的错误使用 Reasonably foreseeable misuse	NA	0	0	0	0	None		No	Yes
5	不充分的副作用警告 Insufficient warning of side effects	NA	0	0	0	0	None		No	Yes
6	不充分的一次性使用器械重复使用后的可能危害 Inadequate warning of hazards likely with re-use of single use devices	包装上警示不明确 The warning on the package is not specific	1	1	1	1	完善一次性警示符 Better the single use warning symbol	包装版面 Package of the layout	No	Yes
7	不正确的测量和其它方面计量 Incorrect measurement and other metrological aspects	NA	0	0	0	0	None		No	Yes
8	与消耗品/附件/其它器械不相容 Incompatibility with consumables/accessories/other devices	NA	0	0	0	0	None		No	Yes
9	锐边、锐角 sharp edges or points	NA	0	0	0	0	None		No	Yes
C7. Inappropriate, inadequate or over-complicated user interface (man/machine communication) 不正确、不充分或过于复杂的用户介面 （人/机交流）										
1	错误或判断错误 Mistakes and judgment errors	NA	0	0	0	0	None		No	Yes
2	重叠和认知检索错误 Lapses and cognitive recall errors	NA	0	0	0	0	None		No	Yes
3	滑移和疏忽(精神或实际的）Slips and blunders (mental or physical)	NA	0	0	0	0	None		No	Yes
4	违反或偏离说明书、程序等 Violation or abbreviation of	NA	0	0	0	0	None		No	Yes

No.	Hazard		Risk Evaluation				Risk Reduction Measure	Evidence	NH	ALOR
	General	Identify hazards	S	O	D	RL				
	instructions, procedures, etc.,									
5	复杂或混淆的控制系统 Complex or confusing control system	NA	0	0	0	0	None		No	Yes
6	含糊的或不清晰的医疗器械状态 Ambiguous or unclear device state	NA	0	0	0	0	None		No	Yes
7	设置、测量或其它信息的含糊或不清晰的显示 Ambiguous or unclear presentation of settings, measurements or other information	NA	0	0	0	0	None		No	Yes
8	结果的错误呈显示 Mispresentation of results	NA	0	0	0	0	None		No	Yes
9	视觉、听觉或触觉的不充分 Insufficient visibility, audibility or tactility	NA	0	0	0	0	None		No	Yes
10	动作控制或实际状态信息显示的图象不清 Poor mapping of controls to action, or of displayed information to actual state	NA	0	0	0	0	None		No	Yes
11	与现存设备相比，模式或图象成问题 Controversial modes or mappings as compared to existing equipment	NA	0	0	0	0	None		No	Yes
D8. Hazards arising from functional failure, maintenance and ageing 功能性失效，维护、老化的危害和形成因素										
1	错误的数据转换 Erroneous data transfer	NA	0	0	0	0	None		No	Yes
2	维护(包括维修后功能检查技术参数不足)的技术参数不足或缺乏 Lack of , or	NA	0	0	0	0	None		No	Yes

No.	Hazard		Risk Evaluation				Risk Reduction Measure	Evidence	NH	ALOR
	General	Identify hazards	S	O	D	RL				
	inadequate specification for maintenance including inadequate specification of post maintenance functional checks									
3	不适当的维护 Inadequate maintenance	NA	0	0	0	0	None		No	Yes
4	缺乏决定器械寿命的因素决定 Lack of adequate determination of end of device life	NA	0	0	0	0	None		No	Yes
5	缺少电气/机械完整性 Loss of electrical / mechanical integrity	NA	0	0	0	0	None		No	Yes
6	不适当的包装(污染和/或器械损坏) Inadequate packaging(contamination and /or deterioration of the device)	NA	1	2	1	2	包装验证 包装检测 Package test and measurement	包装合格证明 包装验证报告 Qualification of the package evidence and test report	No	Yes
7	重复使用或不正确的重复使用 re-use and / or Improper re-use	NA	3	3	3	27	包装上警示说明 Package of warning direction	标签使用说明和语言信息 Label use of direction and language information	No	Yes
8	由于重复使用使用造成的功能恶化(如液/气路的逐渐闭塞、流阻、电导率的变化) Deterioration in function (e.g. gradual occlusion of fluid/gas path, or change in resistance to flow, electrical conductivity) as a	NA	3	3	3	27	包装上警示说明 Package of warning direction	标签使用说明和语言信息 Label use of direction and language information	No	Yes

No.	Hazard		Risk Evaluation				Risk Reduction Measure	Evidence	NH	ALOR
	General	Identify hazards	S	O	D	RL				
	result of repeated use.									
B2. Additional hazards to in vitro diagnostic medical devices 体外诊断医疗器械的额外危害										
1	批次的不均匀性、批次和批次的不一致性 Batch inhomogeneity, batch-to-batch inconsistency	NA	0	0	0	0	None		No	Yes
2	共同的干扰因素 Common interfering factors	NA	0	0	0	0	None		No	Yes
3	延期效应 Carry-over effects	NA	0	0	0	0	None		No	Yes
4	样本标示错误 Specimen identification errors	NA	0	0	0	0	None		No	Yes
5	稳定性问题(在储存中、运输中、使用中、容器第一次打开后) Stability problems (in storage, in shipping, in use, after first opening of the container)	NA	0	0	0	0	None		No	Yes
6	与样本的抽取、准备及稳定性问题 Problems related to taking, preparation and stability of speciments	NA	0	0	0	0	None		No	Yes
7	先决条件的不适当技术规范 Inadequate specification of prerequisites	NA	0	0	0	0	None		No	Yes
8	不适当的试验特性) Inadequate test characteristics	NA	0	0	0	0	None		No	Yes
生产后信息 Post-production information										
	Post-production experience: 严格控制生产过程，重点监测产品生产关键工序。									
	Review of risk management experience: 重点控制高风险点（微生物污染、标签和使用说明不当等）									

缩略词：Abbreviations used

RE	风险评估 Risk Evaluation
S	严重程度 Severity (9 – 非常严重 very severe, 0 –不严重 not severe)
O	发生频率 Occurrence (9 – 经常 often, 0 – 不发生 never)
D	可发现 Detection (9 – 当风险发生时不可能发现 impossible to detect before risk occurs, 0 – 当风险发生时一定可发现 will be certainly detected before risk occurs)
RL	风险等级 Risk Level = 严重性 Severity × 发生频率 Occurrence × 可发现 Detection 1-9: 可忽略的风险，不需进一步行动 neglectable risk, no further actions; 9-24: 中等风险，建议预防措施 moderate: minimal risk, preventive action recommended; 25-48: 中等风险，要求预防措施 moderate risk, preventive action required; >48: 风险通常一般不可接受 risk is usually not acceptable
RRM	风险减少措施 Risk Reduction Measure
NH	新危害发生 New hazard generated (no/ yes - if yes, 如不可接受，写出危害号码 then number of new hazard indicated)
ALOR	风险是否可接受 Acceptable Level of Risk (no/ yes)

JIANGSU KANGBAO MEDICAL EQUIPMENT CO., LTD.	CE technical file I.V.Catheter	Page: 01-01 File No: PL-IVC-TF-A
	13 **Essential Requirements Check**	Date: 20230726 Revision: 04

93/42/EEC including 2007/47/EC **Annex I** **Essential Requirements Check list** **93/42/EEC 包括 2007/47/EC** **附录一　　基本要求检查表** **QMF-MF-33008SHG**	

Product name: **I.V. Catheter**

Type(s)/Model(s): **With wings & injection port（14G—26G）、**
Without wings without injection port（14G—26G）、
With wings without injection port（14G—26G）

Product group: **-----**

Issue date of Technical File: **Revision of Technical File: A/0**

Legal Manufacturer:
法定制造商

江苏康宝医疗器械有限公司
Name

JIANGSU KANGBAO MEDICAL EQUIPMENT CO., LTD. oration
Street 街道
ANYI
Postal code 邮编 225800 Place 地点 BAOYING city

78#, North Suzhong Road, Baoying, Yangzhou, Jiangsu
Country 国家: P.R.China

Accessories:
附件：

Date 日期	*Name Reviewer 1/审核人 1 的名字*	*Signature Reviewer 1/审核人 1 签字*
Date 日期	*Name Reviewer 2/审核人 2 的名字*	*Signature Reviewer 2/审核人 2 签字*

Checklist according to annex I of the Medical Device Directive (MDD) 按医疗器械指令（MDD）附录一的基本要求检查表		A/ NA 适用/不适用	Standards, other directives and other rules applied by manufacturer 制造商引用的标准其它指令或规则	Documentation (test reports, protocols, literature or reason for no applicability) 支持性文件(测试报告，方案，文献或不适用的理由)	Requirements fulfilled (to be filled in by Notified Body) 要求满足(由告机构填写)	Ok / Fail 符合 / 不符合
I.	**General Requirements** 通用要求					
1.	The devices must be designed and manufactured in such a way that, when used under the conditions and for the purposes intended, they will not compromise the clinical condition or the safety of patients, or the safety and health of users or, where applicable, other persons, provided that any risks which may be associated with their intended use constitute acceptable risks when weighed against the benefits to the patient and are compatible with a high level of protection of health and safety. 器械的生产和设计必须保证：按照其预定用途和条件使用，器械不会损害临床条件、或患者安全、或操作者或其他人员的安全和健康；假设与器械预期用途相关的任何风险，与之给患者带来的益处相比，并与健康安全的保护程度相一致，则是可接受的。 This shall include: • reducing, as far as possible, the risk of use error due to the ergonomic features of	A	EN ISO14971:2019 EN ISO 10555-1:2013 EN ISO 10555-5:2013	Risk analysis reports		OK

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	the device and the environment in which the device is intended to be used (design for patient safety), and • Consideration of the technical knowledge, experience, education and training and where applicable the medical and physical conditions of intended users (design for lay, professional, disabled or other users). 应包括： • 尽可能地降低由于器械的人体工学特征和器械预期使用的环境（为患者安全设计的）的错误使用而产生的风险， 和 • 考虑技术知识、经验、教育和培训，预期用户（为非专业人员、专业人员、伤残人员或其他人）的医疗和身体条件。					
2.	The solutions adopted by the manufacturer for the design and construction of the devices must conform to safety principles, taking account of the generally acknowledged state of the art. In selecting the most	A	EN ISO11135:2014 EN ISO14971:2019 EN ISO 10555-1:2013 EN ISO 10555-5:2013	Sterilization certificates Risk analysis reports Alarm system control		OK

Checklist according to annex I of the Medical Device Directive (MDD) 按医疗器械指令（MDD）附录一的 基本要求检查表		A/ NA 适用/不适用	Standards, other directives and other rules applied by manufacturer 制造商引用的标准其它指令或规则	Documentation (test reports, protocols, literature or reason for no applicability) 支持性文件(测试报告，方案，文献或不适用的理由)	Requirements fulfilled (to be filled in by Notified Body) 要求满足(由告机构填写)	Ok / Fail 符合 / 不符合
	appropriate solutions, the manufacturer must apply the following principles in the following order: • eliminate or reduce risks as far as possible (inherently safe design and construction), • where appropriate take adequate protection measures including alarms if necessary, in relation to risks that cannot be eliminated, • Inform users of the residual risks due to any shortcomings of the protection measures adopted. 制造商采用的器械结构和设计方案，必须考虑在当前工艺技术条件下遵守安全原则。 在选择最合适方案时，制造商应按照以下顺序遵守原则： • 尽可能地降低或避免风险（固有的安全设计和结构） • 对无法避免的风险，如适用，采取适当的防护措施，包括必要的报警。 • 告知用户由于所提供防护措施的缺陷而带来的残留风险。			program		
3.	The devices must achieve the performances intended by the	A	EN980:2008	Preclinical study		OK

Checklist according to annex I of the Medical Device Directive (MDD) 按医疗器械指令（MDD）附录一的 基本要求检查表		A/ NA 适用/不适用	Standards, other directives and other rules applied by manufacturer 制造商引用的标准其它指令或规则	Documentation (test reports, protocols, literature or reason for no applicability) 支持性文件(测试报告，方案，文献或不适用的理由)	Requirements fulfilled (to be filled in by Notified Body) 要求满足(由告机构填写)	Ok / Fail 符合 / 不符合
	manufacturer and be designed, manufactured and packaged in such a way that they are suitable for one or more of the functions referred to in Article 1 (2) (a), as specified by the manufacturer. 器械最后必须取得制造商期望获得的功能。器械设计、制造和包装应与第1条(2)(a)制造商所规定的一项或多项功能相适应。		EN ISO11607-1:2020 EN ISO 11607-2:2020 EN ISO 10555-1:2013 EN ISO 10555-5:2013 EN ISO 10993-4:2017 EN ISO 10993-5:2009 EN ISO 10993-10:2013 EN ISO 10993-11:2018	Packing certificate Biological evaluation report		
4.	The characteristics and performances referred to in sections 1, 2 and 3 must not be adversely affected to such a degree that the clinical condition and safety of the patients and, where applicable, of other persons are compromised during the lifetime of the device as indicated by the manufacturer, when the device is subjected to the stresses which can occur during normal conditions of use. 在制造商确定的器械使用寿命期内，在正常使用可能出现的压力下，第1，2，3款指的各项特征和性能应不能影响临床条件、危害患者或其它人员的安全。	A	EN ISO14971:2019 EN ISO11135：2014 EN ISO 10555-1:2013 EN ISO 10555-5:2013	Risk analysis reports Sterilization certificates		OK

Checklist according to annex I of the Medical Device Directive (MDD) 按医疗器械指令（MDD）附录一的 基本要求检查表		A/ NA 适用/不适用	Standards, other directives and other rules applied by manufacturer 制造商引用的标准其它指令或规则	Documentation (test reports, protocols, literature or reason for no applicability) 支持性文件(测试报告，方案，文献或不适用的理由)	Requirements fulfilled (to be filled in by Notified Body) 要求满足(由告机构填写)	Ok / Fail 符合 / 不符合
5.	The devices must be designed, manufactured and packed in such a way that their characteristics and performances during their intended use will not be adversely affected during transport and storage taking account of the instructions and information provided by the manufacturer. 器械设计、生产和包装应当保证器械的特征和性能在运输和储存过程中，只要遵守制造商提供的有关说明和信息，就不会受到重大影响。	A	EN980:2008 EN1041:2008 EN ISO 11607-1:2020 EN ISO 11607-2:2020 EN ISO 10555-1:2013 EN ISO 10555-5:2013	Product description Packing certificate Labelling and language information instructions for use		OK
6.	Any undesirable side effects must constitute an acceptable risk when weighed against the performances intended. 副作用的大小同器械的预期性能相比，是可接受的风险。	A	EN ISO14971:2019	风险分析报告		OK
6a.	Demonstration of conformity with the essential requirements must include a clinical evaluation in accordance with Annex X. 证明符合基本要求必须包括按照附录 X 的临床评估	A	EN ISO14971:2019	Risk analysis reports		OK
II.	**REQUIREMENTS REGARDING DESIGN AND CONSTRUCTION** **设计和结构的要求**					

Checklist according to annex I of the Medical Device Directive (MDD) 按医疗器械指令（MDD）附录一的基本要求检查表		A/ NA 适用/不适用	Standards, other directives and other rules applied by manufacturer 制造商引用的标准其它指令或规则	Documentation (test reports, protocols, literature or reason for no applicability) 支持性文件(测试报告，方案，文献或不适用的理由)	Requirements fulfilled (to be filled in by Notified Body) 要求满足(由告机构填写)	Ok / Fail 符合 / 不符合
7.	Chemical, physical and biological properties 化学、物理和生物特征					
7.1	The devices must be designed and manufactured in such a way as to guarantee the characteristics and performances referred to in Section 1 on the "General requirements". Particular attention must be paid to: • the choice of materials used, particularly as regards toxicity and, where appropriate flammability, • the compatibility between the materials used and biological tissues, cells and body fluids, taking account of the intended purpose of the device. • Where appropriate, the results of biophysical or modelling research whose validity has been demonstrated beforehand. 器械的设计和生产必须保证达到本附录第I部分的通用要求，另外应特别注意： • 合理选择原料，特别是易燃物质和有毒物质的选择； • 从器械预定功能出发考虑所	A	GB/T 14233.2-2005 EN ISO 10555-1:2013 EN ISO 10555-5:2013 EN ISO 10993-4:2017 EN ISO 10993-5:2009 EN ISO 10993-10:2013 EN ISO 10993-11:2009	Bio-compatibility testing Product inspection report		OK

Checklist according to annex I of the Medical Device Directive (MDD) 按医疗器械指令（MDD）附录一的 基本要求检查表		A/ NA 适用/不适用	Standards, other directives and other rules applied by manufacturer 制造商引用的标准其它指令或规则	Documentation (test reports, protocols, literature or reason for no applicability) 支持性文件(测试报告，方案，文献或不适用的理由)	Requirements fulfilled (to be filled in by Notified Body) 要求满足(由告机构填写)	Ok / Fail 符合 / 不符合
	选材料同人体生物组织、细胞和体液的相容性。 • 如适用，事先已确认有效的生物物理学或模型研究的结果					
7.2	The devices must be designed, manufactured and packed in such a way as to minimise the risk posed by contaminants and residues to the persons involved in the transport, storage and use of the devices and to the patients, taking account of the intended purpose of the product. Particular attention must be paid to the tissues exposed and the duration and frequency of the exposure. 器械的设计、制造和包装应当保证器械在运输、储存和使用过程中的污染和残留物对人体危害最低，应特别注意观察暴露于器械下的人体组织及其时间和频率。	A	EN ISO 11607-1:2020 EN ISO 11607-2:2020	Risk analysis reports		OK
7.3	The devices must be designed and manufactured in such a way that they can be used safely with the materials, substances and gases with which they enter into contact during their normal use or during routine procedures; if	A	EN ISO 10555-1:2013 EN ISO 10555-5:2013 EN ISO 10993-4:2017 EN ISO 10993-5:2009 EN ISO 10993-10:2013	Bio-compatibility testing Product inspection report		OK

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	the devices are intended to administer medicinal products they must be designed and manufactured in such a way as to be compatible with the medicinal products concerned according to the provisions and restrictions governing those products and that their performance is maintained in accordance with the intended use. 器械设计和生产必须保证在正常使用和常规过程中接触其它材料、物质和气体不会影响其安全使用；如果器械需要加载其它药品，器械的设计和生产必须保证同该药品相兼容，必须考虑法规对该药品的规定和限制，保证器械达到预定功能。		EN ISO 10993-11:2009			
7.4	Where a device incorporates, as an integral part, a substance which, if used separately, may be considered to be a medicinal product as defined in Article 1 of Directive 2001/83/EC and which is liable to act upon the body with action ancillary to that of the device, the quality, safety and usefulness of the substance must be verified by analogy with the methods specified in Annex I to Directive	NA				OK

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2001/83/EC. 如果某种器械含有某种物质作为其组成部分，而且该物质单独使用时可被认为是2001/83EC第1条含义内的药品，并且它能够帮助该器械对人体产生辅助作用，这种物质的安全性、质量和有效性必须通过2001/83/EC指令附录I涉及的适用方法进行类推来确认。 For the substances referred to in the first paragraph, the notified body shall, having verified the usefulness of the substance as part of the medical device and taking account of the intended purpose of the device, seek a scientific opinion from one of the competent authorities designated by the Member States or the European Medicines Agency (EMEA) acting particularly through its committee in accordance with Regulation (EC) No 726/2004[1] on the quality and safety of the substance including the clinical					

[1] Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency (OJ L 136, 30.4.2004, p. 1). Regulation as last amended by Regulation (EC) No 1901/2006.

Checklist according to annex I of the Medical Device Directive (MDD) 按医疗器械指令（MDD）附录一的 基本要求检查表		A/ NA 适用/不适用	Standards, other directives and other rules applied by manufacturer 制造商引用的标准其它指令或规则	Documentation (test reports, protocols, literature or reason for no applicability) 支持性文件(测试报告，方案，文献或不适用的理由)	Requirements fulfilled (to be filled in by Notified Body) 要求满足(由告机构填写)	Ok / Fail 符合 / 不符合
	benefit/risk profile of the incorporation of the substance into the device. When issuing its opinion, the competent authority or the EMEA shall take into account the manufacturing process and the data related to the usefulness of incorporation of the substance into the device as determined by the notified body. 对于第一段提到的物质，在考虑到该器械的预期用途时确认了该物质作为医疗器械一部分的有效性之后，公告机构应按 Regulation (EC) No 726/2004[1] 法规，就该物质的质量和安全性包括该物质与器械整合的临床受益/风险特性，向成员国指定的一个主管当局或欧洲药品评价署（EMEA）特别是其委员会寻求科学意见。当发表其意见时，主管当局或 EMEA 应考虑公告机构认定的关于该物质与器械整合有效性的生产过程和数据。 Where a device incorporates, as an integral part, a human blood derivative, the notified body shall, having verified the usefulness of the substance as part of the medical device and taking into account the					

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	intended purpose of the device, seek a scientific opinion from the EMEA, acting particularly through its committee, on the quality and safety of the substance including the clinical benefit/risk profile of the incorporation of the human blood derivative into the device. When issuing this opinion, the EMEA shall take into account the manufacturing process and the data related to the usefulness of incorporation of the substance into the device as determined by the notified body. 如果某种器械含有人血制品作为其组成部分，在确认了该血制品作为医疗器械一部分的有效性，并考虑到该器械的预期用途的基础上，公告机构应就该制品的质量和安全性包括该制品与器械整合的临床受益/风险特性，向欧洲药品评价署（EMEA）特别是其委员会寻求科学意见。当发表其意见时，主管当局或EMEA应考虑公告机构认定的关于该物质与器械整合有效性的生产过程和数据。 Where changes are made to an ancillary substance incorporated in a device, in					

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	particular related to its manufacturing process, the notified body shall be informed of the changes and shall consult the relevant medicines competent authority (i.e. the one involved in the initial consultation), in order to confirm that the quality and safety of the ancillary substance are maintained. The competent authority shall take into account the data related to the usefulness of incorporation of the substance into the device as determined by the notified body, in order to ensure that the changes have no negative impact on the established benefit/risk profile of the addition of the substance in the medical device. 如果器械整合的辅助物质发生了变更，特别是关系到其生产过程，公告机构应被通知并向相关的药品主管当局（也就是最初的咨询机构）咨询，以确认辅助物质的质量和安全性得以维持。主管当局应考虑公告机构认定的关于该物质与器械整合有效性的数据，以确保这种变更对已经建立的医疗器械中的增加物质的临床受益/风险特性没有负面影响。					

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	When the relevant medicines competent authority (i.e. the one involved in the initial consultation) has obtained information on the ancillary substance, which could have an impact on the established benefit/risk profile of the addition of the substance in the medical device, it shall provide the notified body with advice, whether this information has an impact on the established benefit/risk profile of the addition of the substance in the medical device or not. The notified body shall take the updated scientific opinion into account in reconsidering its assessment of the conformity assessment procedure. 当相关的药品主管当局（也就是最初的咨询机构）得到关于辅助物质对已经建立的医疗器械中的增加物质的临床受益/风险特性有影响的信息后，应向公告机构提出建议，该信息是否影响已经建立的医疗器械中增加物质的临床受益/风险特性。公告机构应考虑到更新的科学意见，以重新考虑对符合性评价程序的评价。					

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7.5	The devices must be designed and manufactured in such a way as to reduce to a minimum the risks posed by substances leaking from the device. Special attention shall be given to substances which are carcinogenic, mutagenic or toxic to reproduction, in accordance with Annex I to Council Directive 67/548/EEC[2] of 27 June 1967 on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances[3]. 器械的设计和制造，必须将源自器械的物质泄漏的风险降至最低。应当特别注意按1967年6月27日成员国法律中67/548/EEC[2]委员会指令附录I界定的致癌物、诱基因突变物和生殖毒性物质相关的危险物质[3]对分类、包装和标签的法律法规，行政条款的符合。 If parts of a device (or a device itself) intended to administer and/or remove medicines, body	A	ISO14971:2009 EN ISO 10555-1:2013 EN ISO 10555-5:2013	Product design synthetic description Risk analysis reports		OK

[2] Internal note: replaced by (EC) 1272/2008

[3] OJ 196, 16.8.1967, p. 1. Directive as last amended by Directive 2006/121/EC of the European Parliament and of the Council (OJ L 396, 30.12.2006, p. 850).

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liquids or other substances to or from the body, or devices intended for transport and storage of such body fluids or substances, contain phthalates which are classified as carcinogenic, mutagenic or toxic to reproduction, of category 1 or 2, in accordance with Annex I to Directive 67/548/EEC[2], these devices must be labelled on the device itself and/or on the packaging for each unit or, where appropriate, on the sales packaging as a device containing phthalates. 如果器械的一部分（或器械本身）预期用于对身体给药或除药、体液或其它物质，或预期用于运输或存储这些体液或物质，包含有按67/548/EEC[2]指令附录I界定的1类或2类致癌物、诱基因突变物或生殖毒性物质的邻苯二甲酸盐，该器械必须在自身和/或每台的包装上作出标识，及适当时在器械的销售包装上作出含有邻苯二甲酸盐的标识。 If the intended use of such devices includes treatment of children or treatment of pregnant or nursing women, the manufacturer must provide					

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	a specific justification for the use of these substances with regard to compliance with the essential requirements, in particular of this paragraph, within the technical documentation and, within the instructions for use, information on residual risks for these patient groups and, if applicable, on appropriate precautionary measures. 如果器械的预期用途包括对儿童、孕妇或哺乳期妇女的治疗，制造商必须在技术文档和使用说明书中提供具体的使用这些物质的理由，及关于对这些患者群的残留风险，如适用，和合适的防范措施等信息，以符合基本要求，特别是本条的要求。					
7.6	The devices must be designed and manufactured in such a way as to reduce as much as possible, risks posed by the unintentional ingress of substances into the device taking into account the device and the nature of the environment in which it is intended to be used. 考虑到器械和预期使用的环境，器械的设计和生产必须保	A	EN ISO 14971:2019	Risk analysis reports		OK

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	证，最大限度地降低由于异物进入而造成危害的可能性。					
8.	Infection and microbial contamination 感染和微生物污染					
8.1	The devices and their manufacturing processes must be designed in such a way as to eliminate or reduce as far as possible the risk of infection to the patient, user and third parties. The design must allow easy handling and, where necessary, minimise contamination of the device by the patient or vice versa during use. 器械设计和制造工艺应当保证最大限度地降低甚至避免患者、使用者和其他人员之间交叉感染的可能性；器械应当操作简单，必要时，减少患者对器械、器械对患者的接触污染。	A	ISO14971:2019 EN ISO 10555-1:2013 EN ISO 10555-5:2013 EN ISO 11607-1:2020 EN ISO 11607-2:2020	Product design synthetic description Risk analysis reports		OK
8.2	Tissues of animal origin must originate from animals that have been subjected to veterinary controls and surveillance adapted to the intended use of the tissues. 动物源组织必须从对按组织的预期用途被进行控制和监管的动物中取得。	NA				OK

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	Notified Bodies shall retain information on the geographical origin of the animals. 公告机构应保留动物的原生地的信息。 Processing, preservation, testing and handling of tissues, cells and substances of animal origin must be carried out so as to provide optimal security. In particular safety with regard to viruses and other transmissible agents must be addressed by implementation of validated methods of elimination or viral inactivation in the course of the manufacturing process. 对动物组织、细胞和其它动物源物质的加工、贮存、检验和处理，必须提供最可靠的安全保障。特别是病毒和其它传染物质的安全，在生产过程中有采取有效的消除方法或进行病毒灭活。					
8.3	Devices delivered in a sterile state must be designed, manufactured and packed in a non-reusable pack and/or according to appropriate procedures to ensure they are sterile when placed on the	A	EN ISO 11607-1:2020 EN ISO 11607-2:2020 EN 1041:2008 EN ISO 10555-1:2013	Packing certificate Sterilization certificates		OK

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	market and remain sterile, under the storage and transport conditions laid down, until the protective packaging is damaged or opened. 无菌器械的设计、生产和包装应采用一次性使用包装方式，并且在一定工作程序下保证器械上市时处于无菌状态，在贮藏、运输条件下只要包装不破损或开封，能够保持无菌状态。		EN ISO 10555-5:2013			
8.4	Devices delivered in a sterile state must have been manufactured and sterilised by an appropriate, validated method. 无菌器械必须通过专门、有效的方法进行生产和灭菌。	A	EN ISO 11135-1:2014 EN ISO 10555-1:2013 EN ISO 10555-5:2013	Product design synthetic description Sterilization certificates Clean room control		OK
8.5	Devices intended to be sterilised must be manufactured in appropriately controlled (e.g. environmental) conditions. 需要灭菌的器械在专门控制的环境下生产。	A	ISO13485:2016 EN ISO 10555-1:2013 EN ISO 10555-5:2013	Program files Environmental test reports		OK
8.6	Packaging systems for non-sterile devices must keep the product without deterioration at the level of cleanliness stipulated and, if the devices are to be sterilised prior to use, minimise the risk	NA				OK

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	of microbial contamination. The packaging system must be suitable taking account of the method of sterilisation indicated by the manufacturer. 非灭菌器械的包装系统，应当保证产品达到规定的清洁度。如果器械需要在使用前灭菌，应减少器械灭菌前微生物污染的可能性。包装系统必须适合于制造商所指定的灭菌方式。					
8.7	The packaging and/or label of the device must distinguish between identical or similar products sold in both sterile and non-sterile condition. 相同或相似的产品销售时处于无菌状态还是非无菌状态，器械必须具有不同的包装和/或标签。	NA				OK
9.	Construction and environmental properties 结构和环境特征					
9.1	If the device is intended for use in combination with other devices or equipment, the whole combination, including the connection system must be safe and must not impair the specified performance of the devices. Any restrictions on	A	EN ISO 14971:2019	Risk analysis reports Instructions for use		OK

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	use must be indicated on the label or in the instruction for use. 器械如果需要同其它器械或设备配合在一起使用，整个系统应保证安全，包括联接系统必须安全，不得改变器械的预定功能。必须在使用说明或标签上注明使用限制。					
9.2	Devices must be designed and manufactured in such a way as to remove or minimise as far as possible: 器械的设计和生产必须尽可能降低或避免： • the risk of injury, in connection with their physical features, including the volume/pressure ratio, dimensional, and where appropriate the ergonomic features, 由于器械物理性能特性，如体积压力比、外观尺寸、人体工学，对人体造成伤害的可能性。 • risks connected with reasonably foreseeable environmental conditions, such as magnetic fields, external electrical influences, electrostatic discharge,	A	EN ISO 14971:2019	Risk analysis reports		OK

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	pressure, temperature or variations in pressure, and acceleration, 在合理的环境条件下，如电磁场、外部电子干扰，静电放射、大气压、气温以及压力变化和加速度等条件下，对人体造成伤害的可能性。 • the risks of reciprocal interference with other devices normally used in the investigations or for the treatment given, 在治疗或试用时，同其它器械相互干扰对人体造成伤害的可能性。 • risks arising where maintenance or calibration are not possible (as with implants) from ageing of the materials used or loss of accuracy of any measuring or control mechanism. 如果无法维修或矫正(如植入人体后),由于材料老化、测试或控制机能精度不够，对人体造成伤害的可能性。					
9.3	Devices must be designed and manufactured in such a way as to minimise the risks of fire or explosion during normal use and in single fault condition.	NA				OK

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	Particular attention must be paid to devices whose intended use includes exposure to flammable substances which could cause combustion. 器械的设计和生产必须保证，在正常使用情况下或单一故障的情况下，器械不至于起火或爆炸。对在暴露于易燃物质环境下使用的器械必须给予特别注意。					
10.	Devices with a measuring function 具有测量功能的器械					
10.1	Devices with a measuring function must be designed and manufactured in such a way as to provide sufficient accuracy and stability within appropriate limits of accuracy and taking account of the intended purpose of the device. The limits of accuracy must be indicated by the manufacturer. 检测器械的设计和生产必须保证足够的精度和稳定性、符合器械预定功能的要求。制造商必须注明其精度范围。	NA				OK
10.2	The measurement, monitoring and display scale must be designed in line with ergonomic	NA				OK

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	principles, taking account of the intended purpose of the device. 必须根据器械的预定功能，按照人体工学的原理设计器械的度量、监控和显示刻度。					
10.3	The measurements made by devices with a measuring function must be expressed in legal units conforming to the provisions of Council Directive 80/181/EEC[4]. 测量器械必须使用法定度量单位，符合理事会法令80/181/EEC[4]的规定。	NA				OK
11.	Protection against radiation 辐射保护					
11.1 11.1.1	*General* *原则* Devices shall be designed and manufactured such that exposure of patients, users and other persons to radiation shall be reduced as far as possible compatible with the intended purpose, whilst not restricting the application of appropriate specified levels for therapeutic and diagnostic purposes.	NA				OK

[4] OJ No L 39, 15. 2. 1980, p. 40. Directive as last amended by Directive 89/617/EEC (OJ No L 357, 7. 12. 1989, p. 28).

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	器械的设计和生产必须保证在达到预定功能的情况下，尽量减少对患者、使用者和其它人员的辐射，但不限制为治疗和诊断疾病使用规定合理的剂量。					
11.2 11.2.1	*Intended radiation* *预期的辐射* Where devices are designed to emit hazardous levels of radiation necessary for a specific medical purpose the benefit of which is considered to outweigh the risks inherent in the emission, it must be possible for the user to control the emissions. Such devices shall be designed and manufactured to ensure reproducibility and tolerance of relevant variable parameters. 用于特定医疗目的，有的器械辐射危害人体健康的射线，这种器械对患者的治疗作用同射线相比可以为人们所接受。器械辐射剂量必须能够控制，(设计和生产时)必须考虑其可变参数的可重复性和容差。	NA				OK
11.2.2	Where devices are intended to emit potentially hazardous, visible and/or invisible radiation, they must be fitted,	NA				OK

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	where practicable, with visual displays and/or audible warnings of such emissions. 设计器械发射危害性射线，不论射线是否可见，都应根据实际需要安装可见的显示装置和发声的报警装置，指示射线的发射状态。					
11.3 11.3.1	*Unintended radiation* *非预期的辐射* Devices shall be designed and manufactured in such a way that exposure of patients, users and other persons to the emission of unintended, stray or scattered radiation is be reduced as far as possible. 器械的设计和制造应当保证，尽量减少对患者，使用者以及其它人员产生非预期的意外辐射。	NA				OK
11.4 11.4.1	*Instructions* *使用说明* The operating instructions for devices emitting radiation must give detailed information as to the nature of the emitted radiation, means of protecting the patient and the user and on ways of avoiding misuse and of eliminating the risks inherent in	NA				OK

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	installation. 放射性医疗器械应详细说明辐射特性、对患者和操作者的保护措施、任何防止操作错误以及消除由于安装器械带来的潜在危险。					
11.5 11.5.1	*Ionising radiation* *电离辐射* Devices intended to emit ionising radiation must be designed and manufactured in such a way as to ensure that, where practicable, the quantity, geometry and quality of radiation emitted can be varied and controlled taking into account the intended uses. 电离辐射器械的设计和生产必须保证，可以改变和控制电离辐射的数量，形状和质量，满足预定使用功能的实际需要。	NA				OK
11.5.2	Devices emitting ionising radiation intended for diagnostic radiology shall be designed and manufactured in such a way, as to achieve appropriate image and/or output quality for the intended medical purpose whilst minimising radiation exposure of the patient and user. 诊断用电离辐射器械的设计和生产必须保证，在获得清晰图	NA				OK

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	象、提高输出质量、达到预定医疗目的的情况下，尽量减少对患者和使用者的照射。					
11.5.3	Devices emitting ionising radiation intended for therapeutic radiology shall be designed and manufactured in such a way as to enable reliable monitoring and control of the delivered dose, the beam type and energy and where appropriate the quality of the radiation. 治疗用电离辐射器械的设计和生产必须保证，能够有效地监控照射剂量、离子束类型、能量大小以及离子束的质量。	NA				OK
12.	Requirements for medical devices connected to or equipped with an energy source 连接或配备能源的医疗器械的要求					
12.1	Devices incorporating electronic programmable systems must be designed to ensure the repeatability, reliability and performance of these systems according to their intended use. In the event of a single fault condition (in the system) appropriate means should be adopted to	NA				OK

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	eliminate or reduce as far as possible consequent risks 带有可编程系统的器械设计应保证其可重复性、可靠性、满足预定功能的需要。应当采取必要措施、减少因出现单一故障状态而造成危害的可能性。					
12.1a	For devices which incorporate software or which are medical software in themselves, the software must be validated according to the state of the art taking into account the principles of development lifecycle, risk management, validation and verification. 对于合并软件使用的或本身是医疗软件的器械，软件必须考虑研发生命周期、风险管理、确认和验证的原则，按照当前的技术发展水平进行确认。	NA				OK
12.2	Devices where the safety of the patients depends on an internal power supply must be equipped with a means of determining the state of the power supply. 对维系患者安全的器械，内部供电时，应配有电源指示装置，表明电源的供电状况。	NA				OK
12.3	Devices where the safety of the patient depends on an external power supply must include an	NA				OK

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	alarm system to signal any power failure. 对维系患者安全的器械，外部供电时，应增加报警装置，报告电源中断。					
12.4	Devices intended to monitor one or more clinical parameters of a patient must be equipped with appropriate alarm systems to alert the user of situations which could lead to death or severe deterioration of the patient's state of health. 监测患者临床数据的器械，必须配置相应的报警系统，提醒操作者可能导致患者死亡或病情严重恶化的情况。	NA				OK
12.5	Devices must be designed and manufactured in such a way as to minimise the risks of creating electromagnetic fields which could impair the operation of other devices or equipment in the usual environment. 器械的设计和生产必须保证，尽量减少由于产生电磁场，影响其它器械或设备的操作使用造成的危害。	NA				OK
12.6	*Protection against electrical risks* *防止触电危险.* Devices must be designed and	NA				OK

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	manufactured in such a way as to avoid, as far as possible, the risk of accidental electric shocks during normal use and in single fault condition, provided that the devices are installed correctly. 假定器械安装正确，器械的设计和生产必须尽量减少在正常使用和出现单一故障时，意外电击的危险。					
12.7 12.7.1	*Protection against mechanical and thermal risks* *高温和机械防护* Devices must be designed and manufactured in such a way as to protect the patient and user against mechanical risks connected with, for example, resistance, stability and moving parts. 器械的设计和生产必须保证患者、使用者不受机械部件造成的损伤，如阻力部件、稳定性部件和移动性部件造成的损伤。	NA				OK
12.7.2	Devices must be designed and manufactured in such a way as to reduce to the lowest possible level the risks arising from vibration generated by the devices, taking account of technical progress and of the	NA				OK

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	means available for limiting vibrations, particularly at source, unless the vibrations are part of the specified performance. 器械的设计和生产必须保证，根据技术发展水平，采取控制振动(特别是振动源)的措施，最大限度地降低器械振动造成的危害，除非所发出的振动是特定功能的需要。					
12.7.3	Devices must be designed and manufactured in such a way as to reduce to the lowest possible level the risks arising from the noise emitted, taking account of technical progress and of the means available to reduce noise, particularly at source, unless the noise emitted is part of the specified performance. 器械的设计和生产必须保证，根据技术发展水平，采取控制噪音(特别是噪音源)的措施，最大限度地降低器械噪音造成的危害，除非所发出的声音是特定功能的需要。	NA				OK
12.7.4	The terminals and connectors to the electricity, gas or hydraulic and pneumatic energy supplies which the user has to handle must be designed and constructed in such a way as to	NA				OK

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	minimise all possible risks. 操作者接触的电源、气动、气压端口和连接件，设计和生产必须考虑减少各种危险的可能性。					
12.7.5	Accessible parts of devices (excluding any parts or areas intended to supply heat or reach given temperatures) and their surroundings must not attain potentially dangerous temperatures under normal use. 在正常使用的情况下，人体可接触到的器械部件及其周围，温度不得过高，以免造成危险；但不包括专门用于提供热量或必须达到一定温度的部件和区域。	NA				OK
12.8 12.8.1	Protection against the risks posed to the patient by energy supplies or substances 防止能源提供和物资供应造成对患者的危险 Devices for supplying the patient with energy or substances must be designed and constructed in such a way that the flow rate can be set and maintained accurately enough to guarantee the safety of the patient and of the user. 为患者提供能源或物质的器械	NA				OK

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	设计和生产必须保证，器械可以控制流量，保证足够的精度，保证患者和使用者的安全。					
12.8.2	Devices must be fitted with the means of preventing and/or indicating any inadequacies in the flow-rate which could pose a danger. 器械必须配有专门装置，防止出现流量波动给患者带来危险，或出现问题时报警。 Devices must incorporate suitable means to prevent, as far as possible, the accidental release of dangerous levels of energy from an energy and/or substance source. 器械必须配备适当的装置尽量避免能量和/或物质意外增加到危险的程度。	NA				OK
12.9	The function of the controls and indicators must be clearly specified on the devices. 指示器和控制按钮、手柄等必须在器械上予以注明。Where a device bears instructions required for its operation or indicates operating or adjustment parameters by means of a visual system, such information must be understandable to the user and, as appropriate, the	NA				OK

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	patient. 如果器械通过可视系统提供操作说明，通过可视系统显示和修改各种参数，可视系统显示的信息必须能为操作者所理解，必要时患者也应看得懂。					
13.	Information supplied by the manufacturer 制造商提供的信息					
13.1	Each device must be accompanied by the information needed to use it safely and properly, taking account of the training and knowledge of the potential users, and to identify the manufacturer. 考虑到对于潜在使用者的培训和认知，以及识别制造商，每个器械必须附带所需信息，以安全正确使用。 This information comprises the details on the label and the data in the instructions for use. 这些信息器械应在标签或使用说明书具体说明。 As far as practicable and appropriate, the information needed to use the device safely must be set out on the device itself and/or on the packaging for each unit or, where	A	EN ISO 15223-1:2016 EN1041:2008 EN ISO 10555-1:2013 EN ISO 10555-5:2013	Product description Labelling and language information Instructions for use		OK

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	appropriate, on the sales packaging. If individual packaging of each unit is not practicable, the information must be set out in the leaflet supplied with one or more devices. 根据实际需要，在器械上、在每个器械的包装上或在销售包装上都应注明安全使用所需要的操作信息。如果不可能对每个器械单独包装，则应随每一个器械或一定数量的器械提供活页说明。 Instructions for use must be included in the packaging for every device. By way of exception, no such instruction leaflet is needed for devices in Class I or Class IIa if they can be used completely safely without any such instructions. 每个器械的包装中应附带使用说明，但 I 类或 IIa 类器械，如果不需要使用说明书也可以安全使用，可以除外。					

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13.2	Where appropriate, this information should take the form of symbols. Any symbol or identification colour used must conform to the harmonised standards. In areas for which no standards exist, the symbols and colours must be described in the documentation supplied with the device. 根据需要应通过使用标志说明操作信息。器械使用的标志或识别颜色应符合欧洲共同体协调标准。如果没有统一标准，标志和识别颜色的含义必须在器械附带的资料中说明。	A	EN1041:2008 EN ISO 15223-1:2016 EN ISO 10555-1:2013 EN ISO 10555-5:2013	Labelling and language information Instructions for use		OK
13.3	The label must bear the following particulars: 器械标签必须具有下列内容： a) the name or trade name and address of the manufacturer. For devices imported into the Community, in view of their distribution in the Community, the label, or the outer packaging, or instructions for use, shall contain in addition the name and address of the authorised representative where the manufacturer does not have a registered	A	EN ISO 15223-1:2016 EN1041:2008	Labelling and language information Instructions for use		OK

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	place of business in the Community; (a)制造商的名称或商品名以及地址。为了在欧洲共同体内销售，如果制造商在欧共体内没有注册场地，则进口的器械标签、或外包装或使用说明书中应另外注明授权代表的名称和地址。					
	b) the details strictly necessary to identify the device and the contents of the packaging especially for the users; (b) 使用者识别器械和了解包装内容必需的信息；	A	EN ISO 15223-1:2016	Labelling and language information		OK
	c) where appropriate, the word "STERILE"; (c)必要时，注明“已灭菌”字样；	A	EN1041:2008	Instructions for use		OK
	d) where appropriate, the batch code, preceded by the word "LOT", or the serial number; (d)必要时，注明批号或系列号，批号以“LOT”打头；	A	EN ISO 15223-1:2016	Labelling and language information		OK

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	e) where appropriate, an indication of the date by which the device should be used, in safety, expressed as the year and month; e) 必要时，注明器械安全使用的期限，以年和月表示。 f) where appropriate, an indication that the device is for single use. A manufacturer's indication of single use must be consistent across the Community; f) 必要时，注明器械属于一次性使用。制造商的一次性使用标识必须在欧共体内统一。	A A	EN ISO 10555-1:2013 EN ISO 10555-5:2013 EN1041:2008	Instructions for use Certificate of sterilization		OK OK
	g) if the device is custom made, the words "custom made device"; g) 如果属于定作器械，注明“定制器械”字样。	NA				OK
	h) if the device is intended for clinical investigations, the words "exclusively for clinical investigations"; h) 如果属于临床试用的器械，注明“专门用于临床研究”字样	NA				OK

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i) any special storage and/or handling conditions; i) 特殊储存条件和/或管理要求；	NA				OK
j) any special operating instructions; j) 特殊操作说明；	NA				OK
k) any warnings and/or precautions to take; k) 任何警告和/或注意事项	A	EN1041:2008	使用说明		OK
l) year of manufacture of active devices other than those covered by e). This indication may be included in the batch or serial number; l) 有源器械的生产年份，如不为(e)项所含，则也可以包含在批号或系列号内。	NA				OK
m) where applicable, method of sterilisation. m) 如适用，注明灭菌方法。	A	EN1041:2008	Certificate of sterilization		OK
n) in the case of a device within the meaning of Article 1(4a), an indication that the device contains a human blood derivative." n) 若器械涉及第一章 1(4a)条	NA				OK

Checklist according to annex I of the Medical Device Directive (MDD) 按医疗器械指令（MDD）附录一的 基本要求检查表		A/ NA 适用/不适用	Standards, other directives and other rules applied by manufacturer 制造商引用的标准其它指令或规则	Documentation (test reports, protocols, literature or reason for no applicability) 支持性文件(测试报告，方案，文献或不适用的理由)	Requirements fulfilled (to be filled in by Notified Body) 要求满足(由告机构填写)	Ok / Fail 符合 / 不符合
	款，注明器械含有人血制品					
13.4	If the intended purpose of the device is not obvious to the user, the manufacturer must clearly state it on the label and in the instructions for use. 如果器械的预定功能对操作者来说不是显而易见的，制造商在标签和说明书上应当加以清楚阐述。	A	EN1041:2008 EN ISO 10555-1:2013 EN ISO 10555-5:2013	Product description Labelling and language information		OK
13.5	Wherever reasonable and practicable, the devices and detachable components must be identified, where appropriate in terms of batches, to allow all appropriate action to detect any potential risk posed by the devices and detachable components. 当合理和可行时，器械和可拆卸部件必须加以识别，就批量而言，可以采取各种有效方法对器械和拆卸部件带来的潜在风险加以识别。	NA				OK

Checklist according to annex I of the Medical Device Directive (MDD) 按医疗器械指令（MDD）附录一的 基本要求检查表		A/ NA 适用/不适用	Standards, other directives and other rules applied by manufacturer 制造商引用的标准其它指令或规则	Documentation (test reports, protocols, literature or reason for no applicability) 支持性文件(测试报告，方案，文献或不适用的理由)	Requirements fulfilled (to be filled in by Notified Body) 要求满足(由告机构填写)	Ok / Fail 符合 / 不符合
13.6	Where appropriate, the instructions for use must contain the following particulars: 若适用，使用说明书必须包含以下说明： a) the details referred to in 13.3, with the exception of d) and e) a) 本附录第 13.3 款所指除(d)和(e)项以外的各项内容；	NA				OK
	b) the performances referred to in section 3 and any undesirable side effects; b) 本附录第 3 款所指使用性能及其可能带来的副作用。	NA				OK
	c) if the device must be installed with or connected to other medical devices or equipment in order to operate as required for its intended purpose, sufficient details of its characteristics to identify the correct devices or equipment to use in order to obtain a safe combination; c) 如果必须同其它器械或设备一同安装或连接使用，应当详细说明配合使用的器械或设备的特性，以便取得	NA				OK

Checklist according to annex I of the Medical Device Directive (MDD) 按医疗器械指令（MDD）附录一的基本要求检查表		A/ NA 适用/不适用	Standards, other directives and other rules applied by manufacturer 制造商引用的标准其它指令或规则	Documentation (test reports, protocols, literature or reason for no applicability) 支持性文件(测试报告，方案，文献或不适用的理由)	Requirements fulfilled (to be filled in by Notified Body) 要求满足(由告机构填写)	Ok / Fail 符合 / 不符合
	预期的功能。					
	d) all the information needed to verify whether the device is properly installed and can operate correctly and safely, plus details of the nature and frequency of the maintenance and calibration needed to ensure that the devices operate properly and safely at all times; d) 鉴别器械是否正确安装所必要的技术信息，保证准确、安全使用；以及维护和校准器械所必须的技术指标或频率，保证器械长期准确、安全使用的所有信息。	NA				OK
	e) where appropriate, information to avoid certain risks in connection with implantation of the device; e) 对植入人体的器械，如果需要，应加以特别说明，避免出现植入人体器械特有的危险。	NA				OK

Checklist according to annex I of the Medical Device Directive (MDD) 按医疗器械指令（MDD）附录一的 基本要求检查表	A/ NA 适用/不适用	Standards, other directives and other rules applied by manufacturer 制造商引用的标准其它指令或规则	Documentation (test reports, protocols, literature or reason for no applicability) 支持性文件(测试报告，方案，文献或不适用的理由)	Requirements fulfilled (to be filled in by Notified Body) 要求满足(由告机构填写)	Ok / Fail 符合 / 不符合
f) information regarding the risks of reciprocal interference posed by the presence of the device during specific investigations or treatment; f) 在进行特定检查和治疗的过程中，器械产生相互干扰的危险性说明。	NA				OK
g) the necessary instructions in the event of damage to the sterile packaging and, where appropriate, details of appropriate methods of re-sterilisation g) 说明灭菌包装损坏后，器械如何进行处理；如果可能，说明重新灭菌的有效方法。	A	EN1041:2008	Labelling and language information Instructions for use		OK
h) if the device is reusable, information on the appropriate processes to allow reuse, including cleaning, disinfection, packaging and, where appropriate, the method of sterilization of he device to be resterilized, and any	NA				OK

Checklist according to annex I of the Medical Device Directive (MDD) 按医疗器械指令（MDD）附录一的 基本要求检查表		A/ NA 适用/不适用	Standards, other directives and other rules applied by manufacturer 制造商引用的标准其它指令或规则	Documentation (test reports, protocols, literature or reason for no applicability) 支持性文件(测试报告，方案，文献或不适用的理由)	Requirements fulfilled (to be filled in by Notified Body) 要求满足(由告机构填写)	Ok / Fail 符合 / 不符合
	restriction on the number if reuses. Where devices are supplied with the intention that they be sterilized before use, the instructions for cleaning and sterilization must be such that, if correctly followed, the device will still comply with the requirements in Section I). If the device bears an indication that the device is for single use, information on known characteristics and technical factors known to the manufacturer that could pose a risk if the device were to be re-used. If in accordance with Section 13.1 no instructions for use are needed, the information must be made available to the user upon request; h) 可重复使用的器械，应说明准确使用的方法，包括清洁、消毒、包装以及，如适用，对需要再次灭菌器械进行灭菌的方法，重复使用的次数限制。 如果器械预期要在使用前灭菌，按照清洁和灭菌的使用说明书要求正确执行，器械仍符合第 1 部分的要求。					

Checklist according to annex I of the Medical Device Directive (MDD) 按医疗器械指令（MDD）附录一的 基本要求检查表		A/ NA 适用/不适用	Standards, other directives and other rules applied by manufacturer 制造商引用的标准其它指令或规则	Documentation (test reports, protocols, literature or reason for no applicability) 支持性文件(测试报告，方案，文献或不适用的理由)	Requirements fulfilled (to be filled in by Notified Body) 要求满足(由告机构填写)	Ok / Fail 符合 / 不符合
	如果器械附带了一次性使用的标识，制造商已知的由于已知特性以及技术因素使器械重复使用带来风险的信息。如果按 13.1 部分的规定不需要使用说明书，则信息必须应使用者要求而提供。					
	i) Details of any further treatment or handling needed before the device can be used (for example, sterilisation, final assembly, etc.) i) 器械使用前如何进行处理，如灭菌、最后组装等；	NA				OK
	j) in the case of devices emitting radiation for medical purpose, details of the nature, type intensity and distribution of this radiation j) 利用放射线治疗的器械，必须说明放射线的特性、类型、密度和分布	NA				OK
	The instruction for use must also include details, allowing the medical staff to brief the patient on any contra-indications and any precautions to be taken. These details should cover in particular: 使用说明书必须另外说明，					

Checklist according to annex I of the Medical Device Directive (MDD) 按医疗器械指令（MDD）附录一的 基本要求检查表	A/ NA 适用/不适用	Standards, other directives and other rules applied by manufacturer 制造商引用的标准其它指令或规则	Documentation (test reports, protocols, literature or reason for no applicability) 支持性文件(测试报告，方案，文献或不适用的理由)	Requirements fulfilled (to be filled in by Notified Body) 要求满足(由告机构填写)	Ok / Fail 符合 / 不符合
医护人员如何向消患者说明禁忌症和注意事项，具体包括：					
k) precautions to be taken in the event of changes in the performance of the device; k)器械性能发生变化时的注意事项；	NA				OK
l) precautions to be taken as regards exposure, in reasonably foreseeable environmental conditions, to magnetic fields, external electrical influences, electrostatic discharge, pressure or variations in pressure, acceleration, thermal ignition sources etc.; l) 在可预见的使用环境下，在电磁场、外界电流、静电放射、大气压以及大气压发生变化、加速度、热力源等作用下，应当采取的注意事项 m) adequate information regarding the medicinal product or products which	NA NA				OK OK

Checklist according to annex I of the Medical Device Directive (MDD) 按医疗器械指令（MDD）附录一的 基本要求检查表		A/ NA 适用/不适用	Standards, other directives and other rules applied by manufacturer 制造商引用的标准其它指令或规则	Documentation (test reports, protocols, literature or reason for no applicability) 支持性文件(测试报告，方案，文献或不适用的理由)	Requirements fulfilled (to be filled in by Notified Body) 要求满足(由告机构填写)	Ok / Fail 符合 / 不符合
	the device in question is designed to administer, including any limitations in the choice of substances to be delivered; m) 应当详细说明器械加载的药品或其它物质的性能，包括其选择物质的限制范围；					
	n) precautions to be taken against any special, unusual risks related to the disposal of the device; n)处置器械时防止出现特别、意外风险的注意事项。	NA				OK
	o) medicinal substances, or human blood derivatives incorporated into the device as an integral part in accordance with Section 7.4; o)说明第 7.4 款所指同器械结合一体使用的药物或人血制品；	NA				OK
	p) degree of accuracy claimed for devices with a measuring function. p)具有测试功能的器械应说明声称的精度。	NA				OK

Checklist according to annex I of the Medical Device Directive (MDD) 按医疗器械指令（MDD）附录一的基本要求检查表		A/ NA 适用/不适用	Standards, other directives and other rules applied by manufacturer 制造商引用的标准其它指令或规则	Documentation (test reports, protocols, literature or reason for no applicability) 支持性文件(测试报告，方案，文献或不适用的理由)	Requirements fulfilled (to be filled in by Notified Body) 要求满足(由告机构填写)	Ok / Fail 符合 / 不符合
	q) date of issue or the latest revision of the instructions for use. q) 使用说明书最新版本或修订日期	A	EN1041:2008	Labelling and language information Instructions for use		OK

Name: JIANGSU KANGBAO MEDICAL EQUIPMENT CO., LTD.
Add: 78#, North Suzhong Road, Baoying, Yangzhou, Jiangsu Province, P. R. China

JIANGSU KANGBAO MEDICAL EQUIPMENT CO., LTD.	CE technical file I.V.Catheter	Page: 01-01
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序 号	标准号	标准名称
1	EN ISO 10555-1:2013	一次性使用无菌血管内导管 第 1 部分：通用要求
2	EN ISO 10555-5:2013	一次性使用无菌血管内导管 第 5 部分：套针外周导管
3	EN ISO14971: 2019	医疗器械 风险管理对医疗器械的应用
4	EN ISO11135：2014	环氧乙烷的验证和控制程序
5	EN980：2008	包装、标志及说明
6	EN1041：2008	标签和语言信息使用说明
	EN ISO 15223-1:2016	Medical devices -- Symbols to be used with medical device labels,
7	EN ISO10993-1：2018	医疗器械生物学评价 第 1 部分：评价与试验
8	MDD93/42EEC	欧盟医疗器械指令
9	EN ISO11607-1：2020	最终灭菌医疗器械的包装
10	EN ISO11607-2：2020	最终灭菌医疗器械的包装
12	ISO13485：2016	医疗器械 质量管理体系用于法规的要求
13	MEDDEV 212-1 rev 4	医疗器械应用指南
14	EN ISO11737-1：2018	医疗器械灭菌 微生物学方法 第一部分：产品微生物总数的估计
15	EN ISO 10993-4:2017	医疗器械生物学评价 第 4 部分：与血液相互作用试验选择
16	EN ISO10993-5：2009	医疗器械生物学评价 第 5 部分：体外细胞毒性试验
17	EN ISO10993-7：2008	医疗器械生物学评价 第 7 部分：环氧乙烷灭菌残留量
18	EN ISO10993-10：2013	医疗器械生物学评价 第 10 部分：刺激与迟发型超敏反应试验
19	EN ISO10993-11：2018	医疗器械生物学评价 第 11 部分：全身毒性试验
20	EN ISO 14698-1:2003	微生物污染控制 总体要求、方法
21	EN ISO 14698-2:2003	微生物污染数据的解释和评估
22	ENISO 9626:2016	Stainless steel needle tubing for the manufacture of medical devices — Requirements and test methods

Edit: **Audit:** **Approved by:** **Date:**

Name: JIANGSU KANGBAO MEDICAL EQUIPMENT CO., LTD.
Add: 78#, North Suzhong Road, Baoying, Yangzhou, Jiangsu Province, P. R. China

JIANGSU KANGBAO MEDICAL EQUIPMENT CO., LTD.	CE technical file I.V.Catheter	Page: 01-01 File No: PL-IVC-TF-A
	10 Declaration of confirmity	Date: 20230726 Revision: 04

Declaration of Conformity

Manufacturer
Name：JIANGSU KANGBAO MEDICAL EQUIPMENT CO.,LTD

Address：78#， North Suzhong Road Baoying 225800 Yangzhou PEOPLE'S REPUBLIC OF CHINA

European Representative :
Name: **Shanghai International Holding Corp. GmbH(Europe)**

Address: Eiffestrasse 80, 20537 Hamburg Germany

Product Name: Disposable IV catheter

Model：IV CATHETER PEN TYPE、IV CATHETER WITH WINGS AND INJECTION PORT、IV CATHETER WITH WINGS WITHOUT INJECTION PORT；26G、24G、22G、20G、18G、16G、14G.

Classification: Annex IX of MDD Directives :IIa,rule7
Confirmity Assessment route :MDD 93/42/EEC Annex v+ Annex VII

We herewith declare that the above mentioned product meet the provisions of the following EC Council Directive and Standards (MDD/93/42/EEC). The products meet prospective uses and all supporting documentation are retained under the premise of manufacturer. we are exclusively responsible for this Doc.

Directives

General Applicable Directive: MDD 93/42/EEC

Notify Body: TÜV SÜD Product Service GmbH, Ridlerstr.65, D-80339 Munich, Germany

NB ID：0123

CE Certificate NO: G2 050970 0014 Rev.01

CE Certificate issuing date: 2019-10-08

Place, Date: Jiangsu .Baoying

Name: Liu Hui

Name: JIANGSU KANGBAO MEDICAL EQUIPMENT CO., LTD.
Add: 78#, North Suzhong Road, Baoying, Yangzhou, Jiangsu Province, P. R. China

Signature:

Position: Managing Director

Date:20200415

JIANGSU KANGBAO MEDICAL EQUIPMENT CO., LTD.	CE technical file I.V.Catheter	Page: 07-01 File No: PL-IVC-TF-A
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Physical and Chemical Test

Inspection items		Guideline
Physical requirements	The appearance of needle tube	Needle tube should be clean and straight, without any foreign substrate
	Appearance of needle point	Needle point should be sharp, without defects such as burr or hook
	Appearance of catheter	The external surface should confirm to the requirement 4.3 of the YY0285.1-1999
	The appearance of piece	There should be no obvious defects in injection moulding such as feathered edge, burr, plastic fluidity and air bubble on components such as the needle stand, catheter stand, exhaustion connector and cap of the injection site.
	Discrepancy of external diameter of catheter	The acceptable discrepancy of external diameter of catheter should be
	The valid length of the catheter	The valid length of the catheter should be
	The components of the catheter	The components of the catheter should confirm to the requirement 4.4.2 of ISO10555.5-2013
	Taper connector	Catheter stand, mouth of injection site, screw cap should confirm to the requirement GB/T1962-2015.
	External diameter of needle tube	External diameter of needle tube
	The rigidity of the needle tube	The max flexivity should not be more than mm
	The ductility of needle tube	The span should be mm. And there should be no disjunction after 20-time bend
	Corrosion resistance of the needle tube	The needle tube should have good corrosion resistance
	Foreign substrate in needle tube	The inner surface of a needle should be clean. The miscible liquids flowing through the tube should contain no foreign substrate and no defilement

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JIANGSU KANGBAO MEDICAL EQUIPMENT CO., LTD.	CE technical file I.V.Catheter	Page: 07-02
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Physical requirements	Breaking load	Breaking load should not be less than
	Linkage strength	The junction of needle tube and needle stand can endure 20N axial force and hold for 10 second
	Liquor-feeding valve	It should be flexible, making liquor easy to enter the catheter. It should be easy to close the mouth of injection site when stop feeding.
	Leakage	There should be no leakage
	Matching	The cap and mouth of injection site of the I．V．CANNULA with injection should have good sealability and spontaneous falling is not allowed. Detaching Force between should not be less than 15N
Chemical requirements	Deoxidization substrates	The difference of volume of consumed potassium permanganate [c($KMnO_4$=0.002mol/L)] between inspection solution and blank solution should not be more than 2.0mL
	Metal ions	Colour indicated by test solution should not exceed the mass concentration ρ(Pb2+)=1μg/g
	PH	Deference of PH should not be more than 1.5
	EO residua	EO residua of each set of Transfusion system should not be more than 0.5mg

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JIANGSU KANGBAO MEDICAL EQUIPMENT CO., LTD.	CE technical file I.V.Catheter	Page: 07-03
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	16 Testing report	Date: 20230726
		Revision: 04

Biocompatibility studies for I.V.Catheter (Tri-way stopcock, Heparin cap)

Manufacturer: JIANGSU KANGBAO MEDICAL EQUIPMENT CO., LTD. Name of products: I.V.Catheter (Tri-way stopcock, Heparin cap)

Lot No of the sample: 20121013

Sample of each product quantity: 20 set each.

Date of test: 20121015

The company carries out biological compatibility test in accordance with EN30993-1/ISO10993-1 standards. The tests are consigned to Sanitation & Environment Technology Institute, Soochow University for pyrogen, hemolysis and urgent general toxicity test.

1) Cell toxicity test

A) Determine cytolysis (cell death), inhibition of cell growth and other effects caused by devices, materials and/or leach liquor with cell incubation technology.

b) Add certain volume of liquor L-929 cell solution in accordance with up-mentioned test method. Evaluate the lateral toxicity of sample through cell growth and reproduction.

2) Intracutaneous stimulation test:

a) In this test, a proper model is adopted to determine lateral stimulation reaction of device, materials and/or leach liquor on corresponding part or embedded tissue

Such as skin. Test of device, materials and lateral leachable substrates stimulation should

match with used or contacted pathway (such as skin) and duration.

b) A certain volume of leach liquor of product is injected into rabbit skin in accordance with up-mentioned test method. Evaluation reaction of sample on contacted tissue through

3) Skin allergy test

a) In this test, a proper model is adopted to determine lateral contact allergy of device, materials and/or leach liquor.

b) Skin allergy test: In this test, a certain volume of leach liquor of product is used to contact with cavy skin to determine whether the sample cause contact skin allergic reaction.

4) Hemolysis test

In vitro method is adopted to determine red cell cytolysis and releasing degree

of hematoglobin caused by device, materials and/or leach liquor.

Conclusion: There is no lateral toxicity on cell, no stimulation reaction on skin, no allergic reaction, and no hemolysis reaction of products in accordance with test of leach liquor of product carried out by Sanitation & Environment Technology Institute, Soochow University. The biological compatibility of products is qualified.

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I.V.C Test Report of JIANGSU KANGBAO MEDICAL EQUIPMENT CO., LTD. oration No: 260613-ivc-02

Commodity	I.V.Catheter						
Type	I.V.Catheter--- Without wings &without injection port						
Size	22G	-----					
Quantity	20000PCS	------					
Lot No：20121013	Mfg date：20121013	Exp date：20171012	----				
Test basis：ISO10555.5	Check date：20121015		------				

Test items	Requirements							Result
Gauge	14G	16G	18G	20G	22G	24G	26G	
Color	Orange	White	Deep green	Pink	Deep Blue	Yellow	Violet	Confirm
Tube O.D mm	2.0	1.7	1.3	1.1	0.9	0.7	0.6	Confirm
Length（a）:±1.5mm	(51)45	(51)45	45(32)	32(25)	25(19)	19	19	Confirm
Flow Rate : ml/min	300	196	96	61	36	22	15	Confirm
	----	----	----	----	●	----	---	-----
Appearance	Catheter & needle tube shall be smooth, Point shall sharp & free from feather, edges, burrs, hooks and other defects.							

Name: JIANGSU KANGBAO MEDICAL EQUIPMENT CO., LTD.
Add: 78#, North Suzhong Road, Baoying, Yangzhou, Jiangsu Province, P. R. China

Needle tube	Needle shall be made of a rigid material and shall be straight and uniform in cross-section and wall thickness. The fluid pathway in the needle shall be free of unintended obstructions that would prevent flashback and shall be resistant to corrosion.								
Needle hub	The needle hub or another feature shall permit detection of flashback and shall be designed to communicate with the introducer needle tube. If the introducer needle is provided with a removable vent fitting, the needle hub shall terminate in a female fitting with a 6:100 taper complying with ISO549-1.								
Connection force	No parting from needle hub and needle under pulling strength	14G	16G	18G	20G	22G	24G	26G	Confirm
		20N	20N	20N	20N	10N	10N	10N	
		-----	---			●			
	No parting from catheter hub and catheter under pulling strength	14G	16G	18G	20G	22G	24G	26G	Confirm
		15N	8N	8N	5N	5N	3N	3N	
		---	----			●			

Tube breaking strength	0.55-0.75	0.75-1.15	1.15—1.85	≥1.85	Confirm
	≥3N	≥5N	≥8N	≥15N	
	24G,26G	22G,20G	16G,17G,18G	14G	
		●			

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JIANGSU KANGBAO MEDICAL EQUIPMENT CO., LTD.	JIANGSU KANGBAO MEDICAL EQUIPMENT CO., LTD.		
	CE technical file of I.V.Catheter 17 Testing report		
Page: 07-05	File No: PL-IVC-TF-A	Date: 20230726	1Revision: 04

I.V.C Test Report (2-2) of JIANGSU KANGBAO MEDICAL EQUIPMENT CO., LTD. oration No: 260613-ivc-02

Commodity	I.V.Catheter						
Type	Without wings &without injection port						
Size	22G						
Quantity	20000pcs	--------	-------	---------	--------	----------	----------
Lot No：20121013	Mfg date：20121013	Exp date：20171012					
Test basis：ISO10555.5	Check date：20121015						

Test items	Requirements	Result
Injection valve one-direction	When you inject solution through the injection port, solution will be infused into the vein .After injection, the injection port should not be any leaking.	Confirm
Catheter tube	Shall be tough, it would not be snapped and become deformed after testing.	

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	The distal end of catheter tube should be tapered, fit closely to the needle.	
Needle	Surface should be smooth, straight and stiff.	Satisfaction
	Point should be appear sharp ,free from feather, edge, burrs, hooks and other defect.	Satisfaction
	The needle shall be resistant to corrosion.	Satisfaction
Cannula	Surface shall be tough, would not be shaped and become deformed after test.	Confirm
	The distal end of cannula tube should be tapered, fit closely to the needle.	Confirm
Exhausting	Under 20kpa,20-30 ℃ water ,a few bubbles will occur between the exhaust connecter and needle hub.	Confirm
Leakage	Under 20kpa, shut off the other way, add liquid against the normal injection way, it should be no liquid leakage from injection port.	Confirm
Distance: a	When the needle is fully neither extend beyond the heel of the needle bevel the distance A nor be more than 1mm from it.	Confirm
PH value	Difference values between control and sample must be ≤1.0PH.	Confirm
Heavy metals	Total amount≤5ug/ml	Confirm
	Cdh amount≤0.1ug/ml	Confirm
Oxidizable matter	Must be≤1.5ml/0.002Mol KMnO4.	Confirm
Sterility	It should be no pyrogen	Confirm
Pyrogen	There should be no pyrogen	Confirm
EO residual	EO residua of each set of transfusion system should not be more than 10ug/g	Confirm

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Original record of EO sterile PL-EO-12-2-1013

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JIANGSU KANGBAO MEDICAL EQUIPMENT CO., LTD.

EO Sterilizer	No ： 0218 Size ： HMG-C--15					
	Supplier ： Jiangying Huaqing Machinery Factory					
BI	Name ： ATCC9372		Supplier ： HANGZHOU FUJIE CORP			
	Quantity ： 37		Lot ： 20120416			
	Products			Quantity	Sterile Lot	
Poly Medical	I.V.C—PEN-LIKE			20cartons	20121015	
Poly Medical	3-way stopcock with 100extension tube			30cartons		
Poly Medical	Heparin cap			30cartons		
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Record of EO sterile						
Pretreatment	Temp	42℃				
	Time	120min	Start	9：00	End	11：00
	Humidity	50％RH	Start	9：00	End	11：00
Sterile	Temp	48.5-55℃	Humidity	42—57.8％RH		
	Vacuum	-18Kpa	Start	11：00	End	11：05
	Vacuum rate	2.0kpa/min	EO concentration	600mg/l		
	Does	9KG				
	Keep Temp time	8hr	Start	11：05	End	19：05
	Keep Temp start time	8hr	Start	11：05	End	19：05
	Three times exchange air	Vacuum	-10KPa	Vacuum rate	2.0KPA/min	
		Start	19:05	End	19:35	
		Packing	Packaging intact, not broken			
	Ventilation	1hr	Start	19：35	End	20：35

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1, product review:

1.1 I.V.Catheter is not a first clinical products, the use of more than eighty years history. It

adopted by the raw material for polymer materials and medical stainless steel material

1.2 management representatives can retrieve the related clinical data, using literature for risk assessment.

2, product intended use

I.V.C.ATHETER in clinic as an infusion liquid instruments used, itself does not have medicinal properties, users will not be absorbed by the organization. Its intended use is as follows:

I.V.Catheter is 2 for 2 in the human body vein injection, transfusion and blood transfusion - together with other medical device for single us.

3, the product history is introduced:

Indwelling needle is not a first clinical products, the use of more than eighty years history, the main material is PP, PC, PE, FEP, ABS, and SUS304 level of medical materials. The materials of the products are widely used in clinical. No death caused by indwelling needle using these materials or worsens its health serious potential accident, death or health deterioration.

4, the company's product introduction:

The company's production and sales of history, the third party on the company's production capacity, production environment and the quality management system recognition show that my company can guarantee the safety of the products.

5, product sales and customer information feedback:

The products sell well in domestic and the Americas, Asia and other countries, has never received customer because of the physical and chemical indicators of our products is unqualified, the pyrogen test is unqualified complaints, such as more no medical accidents.

6 after the production information

Clinical evaluation by the management representative collects information of product production, after a year, and to evaluate each year and the update on clinical data summary.

7, product risk conclusion

Risk analysis, for raw materials and production process of the risk are analyzed, and the possible risk taking effective control measures to reduce the risk to an acceptable range, using a value greater than the risk of the product.

To sum up, our company produces the I.V.Catheter product, its use value greater than the risk, can be used as medical apparatus and instruments used in clinical

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1. Purpose:

In order to ensure the products after the delivery of customer, the product of any changes or quality problem can quickly take corrective and preventive actions, and promptly notify the customer the local drug administration and the notified body, when necessary to withdraw the batch products at the same time, lest cause adverse consequences.

2. Scope:

This procedure is applicable to the company's products after the delivery, product changes or any form of quality problems, responsibilities, procedures and methods of the departments concerned.

3. Duties and responsibilities

3.1 Supply and marketing section responsible for product market tracking after delivery, handling customer complaints related matters, and transfer the information to the relevant departments.

3.2 Products division is responsible for any changes of technical product review (including changes in the operating instructions).

3.3 The quality department is responsible for the processing of customer complaints and returns, product withdrawal, and the relevant departments to formulate corrective and preventive measures, and supervise the relevant departments to organize the implementation and verification.

3.4 Management representative is responsible for contact with customers, food and drug administration and the notified body, medical apparatus and instruments announcements.

4. Process

4.1 Product changes and announcements of medical equipment

4.1.1 That changes in the product mainly includes

(a) Product standards revision and change;

(b) The performance of the main material change;

(c) Technical parameters change;

(d) Unit of packaging material and method of change; (operation instruction)

(e) Product changes have conflict with customer orders;

(f) Process major improvement;

(g) Because of the change need to change the technical documentation.

4.1.2：When any of these change, all should notice to the customer. (When it is necessary to the local food and drug administration, department of health or notified body notices) announcement content mainly includes:

(a) Changes before and after the description of the situation;

(b) Changes are to improve the product quality or falling;

(c) Corrective and preventive measures and effects of the changes, the authentication;

(d) Other necessary instructions

4.2 Product withdrawal and medical apparatus and instruments announcements

4.2.1：The condition of product withdrawal

(a) Customer complaints reflect the quality of the problem involves a batch of products sold;

(b) Customer complaints reflect the quality of the problem involves the use of safe and reliable effectiveness;

(c) Sampling period for sample products of the company found that main performance cannot meet the requirements of a batch of product.

4.2.2 The customer's complaints

Customer complaint investigation and evaluation of the

(a) There may be two situations: the product is unqualified, wasn't up to specification requirements; another kind of qualified products, customers is not satisfied, then could reflect is the defect of design or instruction about unclear cause user improper use;

(b) The quality department is responsible for the complaint investigation report, the report content has the following several aspects:

(1) Product name, model, specification;

(2) The date of receipt of the complaint;

(3) Or accept complaints by way of channels;

(4) The background of the complainant, addresses, known;

5. The nature of the questions;

6. Survey results;

7. The reasons of Non-take measures

8. Investigators;

9. Reply to the complainant.

Products need to withdraw when the medical advice of content:

(a) The quality problems involved in the product batch number, location, sales amount;

(b) To withdraw treatment reason and treatment scheme;

(c) Can not withdraw the reasons and treatment of the local solution; (d) may produce harm and then to take measures.

4.2.3 The management representative responsible for drafting medical advice notice

4.2.4 product withdrawal process:

(a) To withdraw the products should be in the isolation room special custody;

(b) The quality department sent a classification test, statistical data;

(c) Analysis;

(d) Handling opinions, destroyed.

4.2.5 Withdraw products processing result, again notice the customer by a representative of the quality department and notified body

4.3 A report on the adverse events

Such as due to the serious defects of the products of our company customers to use when serious medical accident, the company will be governed by the provisions of the "alert system control program".

4.3 This procedure, the records shall be kept in quality department.

5. relative documents

5.1 Improving the control program

5.2 Service control procedure

5.3 Several provisions on the management quality accident report

5.4 About the company product recovery management system

5.5 Return goods management system

6. records

6.1 Medical devices notice	PL-QR—851—01
6.2 Product continuation and withdraw report	PL-QR—851—02
6.3 Product outage notice	PL-QR—851—03
6.4 Initial reports "Adverse events"	PL-QR—851—04
6.5 Adverse events	PL-QR—851—05

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