



Compliance Report

Applicant: Jiangsu Kangjie Medical Devices Co., Ltd.
Address: Shengao Town People Village, Jiangyan District, Taizhou City, Jiangsu Province, China.
Product: Non-Vacuum Blood Collection Tubes, Disposable Sterile Swabs, Vacuum Blood Collection Tubes
Type: See Annex of details
Product Classification: Other

The submitted technical files including test report of the above products have been reviewed against the self declaration requirements of conformity for CE marking according to Annex II & III of the 98/79/EC In Vitro Diagnostic Medical Devices Directive.

The review result of the technical files and test report support the self declaration for the devices listed above. The test report and the technical files are the annex of this report and should be used together.

Where the manufacturer affix's the CE marking to the product listed they must ensure that all the requirements of the appropriate EU directive(s) have and continue to be met.

This report is not a certificate of conformity.

No. **02751**

Initial Issue Date: **24 July 2017**

Tony Chen

General Manager (Signature)

This report is the property of NQA and should be returned to NQA upon request.



Annex to Report (No. 02751)

Jiangsu Kangjie Medical Devices Co., Ltd.

Name	Product	Model
Non-Vacuum Blood Collection Tubes	Plain Tube	0.5-10 ml
	EDTA Tube	0.5-10 ml
	Gel & Clot Activator Tube	0.5-10 ml
	Pro-coagulation Tube	0.5-10 ml
	Sodium Heparin Tube	0.5-10 ml
	Lithium Heparin Tube	0.5-10 ml
	PT Tube	0.5-10 ml
	ESR Tube	0.5-10 ml
	Glucose Tube	0.5-10 ml
Disposable Sterile Swabs	/	Male, Female
Vacuum Blood Collection Tubes	Plain Tube	13x75mm、 13x100mm、 16x100mm
	EDTA Tube	13x75mm、 13x100mm、 16x100mm
	Gel & Clot Activator Tube	13x75mm、 13x100mm、 16x100mm
	Pro-coagulation Tube	13x75mm、 13x100mm、 16x100mm
	Sodium Heparin Tube	13x75mm、 13x100mm、 16x100mm
	Lithium Heparin Tube	13x75mm、 13x100mm、 16x100mm
	PT Tube	13x75mm、 13x100mm、 16x100mm
	ESR Tube	13x75mm、 13x100mm、 16x100mm 、 8x120mm
	Glucose Tube	13x75mm、 13x100mm、 16x100mm

This annex is only valid if attached to the report mentioned above.

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