Compliance Report

Applicant:	Shijiazhuang Kang Weishi Medical Instrument Co., Ltd
Address:	No 95, Yuanshi Street, Yuanshi County, Shijiazhuang, Hebei Province.
Product:	Disposable Human Venous Blood Collection Container
Type:	See annex for 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. **02606**
Initial Issue Date: **13 Sep 2016**

Tony Chen

General Manager (Signature)

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

Annex to Report (No. 02606)

Shijiazhuang Kang Weishi Medical Instrument Co., Ltd

Product Name	Type
Disposable Human Venous Blood Collection Container	No additive(0.5ml,3ml,4ml,5ml,7ml,8ml,10ml), Coagulant(0.5ml,3ml,4ml,5ml,7ml,8ml,10ml) Separation gel/coagulant(3ml,4ml,5ml,7ml,8ml,10ml) EDTA-K2(0.5ml,2ml,3ml,5ml,10ml) EDTA-K3(2ml,3ml,5ml) Sodium citrate (1:9)(2ml,3ml,5ml,10ml) Sodium citrate (1:4)(1.6ml,2ml,3ml) Heparin sodium(0.5ml,3ml,4ml,5ml,10ml) Heparin lithium(0.5ml,3ml,4ml,5ml,10ml)

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

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