



China

CE Technical Documentation Review Report(page1/2)

(According to IVDD Directive 98/79/EC)

Report No. TFR-BJ-65764

The Manufacturer

Hebei Xinle Sci&Tech Co.,Ltd

No.189,Nanhuan Road,050700 Xinle City,Hebei Province

PEOPLE'S REPUBLIC OF CHINA

Has Established CE Technical Documentation for the Following Products

Single-use containers for human venous blood specimen collection

Model: see 2nd page(total 2 pages)

This report is issued on a voluntary basis. It confirms that the CE technical documentation (No. XL-CE.JS-02-01/Version:B /Dec 30 ,2013) of the listed products is complete with regard to the requirements of Annex III section 3 of Directive 98/79/ EC excluding quality system documentation. Detail products covered under the technical documentation are described in this report. This report would be re-assessed before :Sep 11,2017.

Issue Place:

Medical, Health Service Dept.

TÜV SÜD China, Beijing Branch

Issue Date:

Sep 18,2014



Any significant changes in design or construction of the product or amendments to the directive or standards applied may render this report invalid. Also, this report is only valid in combination with ISO13485 certificate issued by TÜV SÜD.



China

CE Technical Documentation Review Report(page2/2)

| | | |
|--|---|---|
| Single-use containers for human venous blood specimen collection | Sterile Plain Tube | 1ml、 2 ml、 3ml、 4ml、 5ml、 6 ml、 7ml、 8 ml、 9 ml、 10ml |
| | Sterile Gel+clot Activator Tube | 3ml、 3.5ml、 4ml、 5ml、 6 ml、 7ml、 8 ml、 8.5 ml |
| | Sterile Gel+K ₂ EDTA Tube | 2 ml、 3ml、 3.5ml、 4ml、 5ml、 6 ml |
| | Sterile blood preservation Tube | 2 ml、 2.5ml、 3ml、 3.5ml、 4ml、 4.5ml、 5ml、 5.5ml、 6ml、 7ml、 8ml、 8.5ml |
| | Sterile Pro-coagulation Tube | 2 ml、 3ml、 4ml、 5ml、 6 ml、 7ml、 8 ml、 9 ml、 10ml |
| | Sterile ESR Tube | 1.28ml、 1.6ml、 1.8ml、 2ml、 2.4ml、 3ml、 3.2 ml、 4ml、 5ml |
| | Sterile PT Tube | 1.8ml、 2ml、 2.7ml、 3ml、 3.6ml、 4ml、 4.5ml、 5 ml |
| | Sterile K ₂ EDTA Tube | 1ml、 2 ml、 3ml、 4ml、 5ml、 6 ml、 7ml、 8 ml、 9 ml、 10ml |
| | Sterile K ₃ EDTA Tube | 1ml、 2 ml、 3ml、 4ml、 5ml、 6 ml、 7ml、 8 ml、 9 ml、 10ml |
| | Sterile Heparin Tube | 1ml、 2 ml、 3ml、 4ml、 5ml、 6 ml、 7ml、 8 ml、 9 ml、 10ml |
| | Sterile Heparin Tube | 1ml、 2 ml、 3ml、 4ml、 5ml、 6 ml、 7ml、 8 ml、 9 ml、 10ml |
| | Sterile Sodium Fluoride/ Potassium Oxalate Tube | 2 ml、 3ml、 4ml、 5ml |
| | Sterile Preservative of Blood Glucose Tube | 2 ml、 3ml、 4ml、 5ml |
| | Sterile Sodium Fluoride/ Heparin Tube | 2 ml、 3ml、 4ml、 5ml |
| Sterile Sodium Fluoride/ EDTA Tube | 2 ml、 3ml、 4ml、 5ml | |