



Compliance Report

Applicant: SHANDONG CHENGWU HUABO MEDICAL EQUIPMENT CO., LTD.

Address: No. 3 Yingbin Road, Development of Dangji Town, Chengwu County, Heze City, Shandong

Product: Disposable Blood Collection Tube, Urine Cup, Disposable Test Tube, Petri Dish, Disposable Trace Collect Blood Tube, Disposable Virus Sampling Tube

Type: See Annex

Product Classification: Others

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. **03219**
Initial Issue Date: **22 May 2020**

A handwritten signature in black ink that reads 'Betty Bao'.

Signer



Annex to Report (No. 03219)

SHANDONG CHENGWU HUABO MEDICAL EQUIPMENT CO., LTD.

Product Name	Type
Disposable Blood Collection Tube	EDTAK2: 13*75, 13*100, 16*100
	EDTAK3: 13*75, 13*100, 16*100
	Sodim Citrate 9NC: 13*75, 13*100, 16*100
	EDTA/Sodium Fluoride: 13*75, 13*100, 16*100
	Plain Tube: 13*75, 13*100, 16*100
	Gel&Clot Activator: 13*75, 13*100, 16*100
	Clot Activator: 13*75, 13*100, 16*100
	Sodium Citrate 4NC: 13*75, 13*100, 16*100, 8*120
	Heparin Sodium: 13*75, 13*100, 16*100
	Lithium Heparin: 13*75, 13*100, 16*100
	Gel&EDTAK2: 13*75, 13*100, 16*100
	Gel&EDTAK3: 13*75, 13*100, 16*100
	Gel&Heparin Sodium: 13*75, 13*100, 16*100
Gel&Lithium Heparin: 13*75, 13*100, 16*100	
Gel&Sodium Citrate: 13*75, 13*100, 16*100	
Gel&ACD: 13*75, 13*100, 16*100	
Urine Cup	40ml, 60ml, 80ml
Disposable Test Tube	12*75, 12*100, 13*75, 13*100, 15*100, 16*100
Petri Dish	35cm, 70cm, 90cm
Disposable Trace Collect Blood Tube	20, 40, 60, 80, 100ul; 0.1ml,0.2ml,0.25ml,0.5ml
Disposable Virus Sampling Tube	A-1.0、A-2.0、A-2.5、A-3.0、A-3.5、A-4.0、A-4.5、 A-5.0、A-5.5、A-6.0
	B-1.0、B-2.0、B-2.5、B-3.0、B-3.5、B-4.0、B-4.5、 B-5.0、B-5.5、B-6.0

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