

Compliance Report

Applicant: Yangzhou Chuangxin Medical Device Factory

Address: YADA Road, Touqiao Town, Hanjiang District, Yangzhou,

Jiangsu, China

Product: Urine Cup, Stool Cup, Petri Dish, Test Tube

Type: 20ml, 30ml, 40ml, 50ml, 60ml, 90ml, 100ml, 120ml, 200ml;

20ml, 30ml, 40ml, 50ml, 60ml, 90ml, 100ml, 120ml, 200ml;

 Φ 150, Φ 90, Φ 70, Φ 60; 12×75, 12×100, 13×75, 13×100,

15×100, 16×100, 25×95, 25×150.

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. 02584

Initial Issue Date: 15 Aug 2016

Tony Chen

General Manager

(Signature)