CECS Center Europe Certification Service

Certificate No. CECS/02012033105D

VERIFICATION OF IVD COMPLIANCE

EU COUNCIL DIRECTIVE 98/79/EC

Applicant	:	Yangzhou Chuangxin Medical Device Factory
Address	:	YADA Road, Touqiao Town, Hanjiang District, Yangzhou,Jiangsu, China.
Manufacturer	:	Yangzhou Chuangxin Medical Device Factory
Address	:	YADA Road, Touqiao Town, Hanjiang District, Yangzhou,Jiangsu, China.
Sample Name	:	Urine cup, Sputum cup, Sample cup, Centrifuge tube, Urine cup, Sputum cup, Sample cup, Centrifuge tube, Sucker box, Slide table, Centrifugal tube table, Pipette.
Model	:	CX-DB, CX-TB, CX-XB, CX-LX, CX-HJ, CX-XT, CX-BP, CX-GP, CX-nD, CX-XTH, CX-BPH, CX-LXH, CX-XG
Test Report No.	:	XMT020121008W/IVD
Codes/Standards Applied	:	EN ISO 14971: 2009; EN 980-2008; EN 1041-2008; EN ISO 13485:2003; EN ISO 12771:1997; EN ISO 24998:2008
Remarks	:	The sample meets the requirements of the above standards.
Date Of Issuance	:	Apr 01, 2012
Conclusion	:	We Confirm That The Technical Construction File And Manufacturing, Inspection And Testing Processes For Above Mentioned Sample Comply With The Essential Safety Requirements of EU In Vitro Diagnostic Medical Devices Directive 98/79/EC Applied Codes And Standards.

President of CECS : Robert Owen

Signature

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