



## Verification of Conformity

Applicant: Suzhou shengtian biotechnology co. LTD  
Address: F2, Unit 2, B3, No. 58, Dongfu Road, Suzhou Industrial Park, Suzhou City, Jiangsu Province, 215000, China  
Product(s): sampling swab kits  
Type(s): AR100, AR105, AR120, AR121, AR150, ARY150, AR180, GAR150, GARY150, GPRY150, PRY150, PN200, APN170, MM100, MM150, PM150, PM100, GPM150, GPSM150, GPM100, PX150, PX100, PSX150, PSX100, GPX150, GPSX150, GPX100, GPSX100, PJ100, PJ125, PJ160, PHM110, PPE200  
Product Classification: Class I

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 In Vitro Diagnostic Medical Devices Directive (98/79EC).

*Standard(s) used for showing compliance with the essential requirements in the specified directive(s):*

Standard(s): EN ISO 14971:2012; EN ISO 18113-1:2011;  
EN ISO 18113-3:2011; EN ISO 15223-1:2016

The review result of the technical files and test report support the self declaration for the devices listed above. 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.

**SUNGO Cert GmbH**

