



Compliance Report

Applicant: Saining (Suzhou) Biotechnology Co., Ltd.
Address: Workshop 16, Lianfa Industrial Park, 158 Hongye Road,
Suzhou Industrial Park, Jiangsu Province, China

Product: PCR SINGLE TUBE, PCR 8 STRIP TUBE, CAPS FOR PCR 8 STRIP TUBE,
PCR 96 WELL PLATE, CENTRIFUGE TUBE, NON FILTERED TIP, FILTER
TIP, CONDUCTIVE TIP, MICRO CENTRIFUGE TUBE, SAMPLE STORAGE
TUBE, DEEP HOLE PLATE, TIP COMB, CELL CULTURE PLATE, TISSUE
CULTURE DISH, CELL CULTURE BOTTLE, CRYOGENIC VIAL,
SEROLOGICAL PIPETTE

Type: See Annex

Product Classification: Other

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. **03256**

Initial Issue Date: **07 April 2021**

Signer





Annex to Report (No. 03256)

Saining (Suzhou) Biotechnology Co., Ltd.

Product Name	Type
PCR SINGLE TUBE	0.2ml
PCR 8 STRIP TUBE	0.1ml,0.2ml
CAPS FOR PCR 8 STRIP TUBE	0.1ml,0.2ml
PCR 96 WELL PLATE	0.1ml half skirt,0.2ml half skirt
CENTRIFUGE TUBE	15ml,50ml
NON FILTERED TIP	10 μ l,200 μ l,300 μ l,1000 μ l,1250 μ l
FILTER TIP	10 μ l,200 μ l,300 μ l,1000 μ l,1250 μ l
CONDUCTIVE TIP	10 μ l,200 μ l,1000 μ l
MICRO CENTRIFUGE TUBE	0.6ml,1.5ml,2.0ml
SAMPLE STORAGE TUBE	0.5ml,1.5ml,2.0ml
DEEP HOLE PLATE	2.2ml square well round bottom,2.2ml square well V bottom
TIP COMB	8 strip
CELL CULTURE PLATE	6 well, 12 well,24 well,48 well ,96 well
TISSUE CULTURE DISH	100mm,60mm,35mm
CELL CULTURE BOTTLE	225cm ² ,175cm ² ,75cm ² ,25cm ²
CRYOGENIC VIAL	1.2ml,1.5ml,2.0ml,5ml
SEROLOGICAL PIPETTE	1ml,2ml,5ml,10ml,25ml,50ml

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