



Compliance Report

Applicant: Wuxi NEST Biotechnology Co., Ltd.
Address: No. 530 Xida Road, New District, Wuxi, Jiangsu, China

Product: Cell Culture Plate, Cell Culture Dish, Cell Culture Flask, Centrifuge Tube, Pipette Tip, PCR Tube & Plate, BioFactory (Multilayer Cell Culture Container), Serological Pipette, Cryogenic Vial, Petri Dish, Erlenmeyer Flask, Cover Glasses, Pasteur Pipette, Elisa Plate, Deep Well Plate, Vacuum Filtration System, Disposable sampler, Specimen collection swab

Type: See annex for details

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.

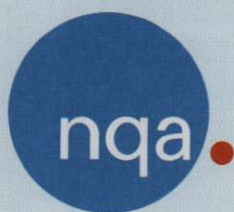
The review result of the technical files and test report support the self declaration for the devices listed above. The test report and the technical files are the annex of this report and should be used together.

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. 03144
Initial Issue Date: 18 Feb 2020
Reissue Date: 25 Mar 2020

Signer



Annex to Report (No. 03144)

Wuxi NEST Biotechnology Co., Ltd.

Product Name	Type
Cell Culture Plate	6 Well /12 Well /24 Well /48 Well / 96 Well /384 Well; Flat Bottom/U-Bottom/V-Bottom; Tissue Culture Treated/Non-treated.
Cell Culture Dish	35 mm /60 mm /100 mm /150mm; Tissue Culture Treated/Non-treated.
Cell Culture Flask	25 cm ² /75 cm ² /175 cm ² /225cm ² ; Plug Seal Cap/Vent Cap; Tissue Culture Treated/Non-treated.
Centrifuge Tube	0.6 mL /1.5 mL /2.0 mL /5.0 mL /15 mL /50mL; Clear/Amber;
Pipette Tip	10 μ l /200 μ l /300 μ l /1000 μ l /1250 μ l; Sterile/Non-sterile.
PCR Tube & Plate	0.1 mL /0.2mL; White/Transparent; No Skirt/Semi Skirt/Full Skirt.
BioFactory (Multilayer Cell Culture Container)	1 Layer /2 Layer /5 Layer /10 Layer / 40Layer; Double Wide Mouth/Double Narrow Mouth/One Wide Mouth & One Narrow Mouth.
Serological Pipette	1 mL /2 mL /5 mL /10 mL /25 mL /50mL
Cryogenic Vial	0.5 mL /1.2 mL /2.0 mL /3.0 mL /4.0 mL /5.0mL; External Thread/Internal Thread.
Petri Dish	35 mm /60 mm /65 mm /90 mm /100 mm/ 150mm
Erlenmeyer Flask	125 mL /250 mL /500 mL /1000 mL / 2000 mL /3000 mL /5000mL; Plug Seal Cap/Vent Cap.
Cover Glasses	14 mm /15 mm /18 mm /20 mm /25mm
Pasteur Pipette	1 mL /2 mL /3mL
Elisa Plate	Detachable/Undetachable
Deep Well Plate	0.36 mL /0.4 mL /0.5 mL /1.0 mL /1.6 mL /2.0 mL /2.2 mL /3.5 mL /4.6mL; Round Well/Square Well; U-Bottom/V-Bottom.
Vacuum Filtration Systems	250 mL /500mL; PES/PVDF/MCE/CA.
Disposable sampler	NSM02
Specimen collection swab	/

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

This report is the property of NQA and should be returned to NQA upon request.