



DECLARATION OF CONFORMITY

Regarding In Vitro Diagnostic Directive (98/79/EC)

Manufacturer: NANTONG TIANYE LABWARE CO., LTD.

Registered Address: No.96, Rongsheng Road, Nantong City, Jiangsu Province, China

Operation Address: Group 16, Sanhe Village, Binjiang Street, Haimen City, Nantong City, Jiangsu Province, China

EC Representative: SUNGO Europe B.V.

Address: Olympisch Stadion 24, 1076DE Amsterdam, Netherlands

Product Name: See Annex

Specification: See Annex

Classification: Others (IVDD)

Conformity Assessment

Procedure: Annex III of In Vitro Diagnostic Directive (98/79/EC)

We herewith declare that the above-mentioned products meet the requirements of in Vitro Diagnostic Directive (98/79/EC) and the following harmonized standards.

EN ISO 14971:2019

EN ISO 18113-1:2011

Signature:

Name/ Position: MAO SHUILAN / GM

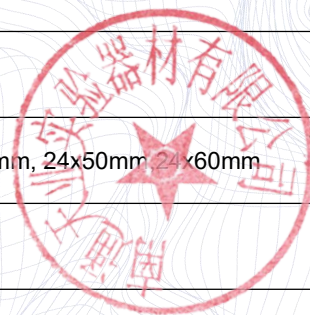
Date: 2021/6/28

Place: Nantong / China

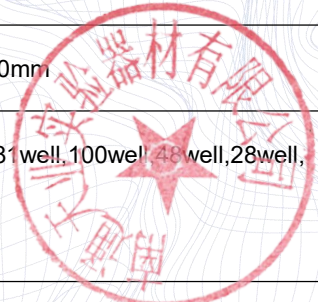


Annex

Product Name	Model/Specification
Centrifuge tube	0.2ml, 0.5ml, 1.5ml, 2ml, 5ml, 7ml, 10ml, 15ml, 50ml
Cryovial tube	0.5ml, 1ml, 1.5ml, 1.8ml, 2ml, 4ml, 5ml, 10ml
Pipette tip	10ul, 200ul, 1000ul, 1250ul, 5ml, 10ml
Pipette tip box	96well, 100well, 48well, 28well
Test tube	10x75, 12x75, 13x75, 12x100, 13x100, 15x100, 16x100, 16x102, 16x150
Test tube stopper	12mm, 13mm, 15mm, 16mm
Petri dish	35x15mm, 60x15mm, 70x15mm, 90x15mm, 100x100mm, 150x15mm
Tissue culture plate	96well, 24well, 12well, 6well
Inoculation loop	1ul, 10ul, 1ul+10ul
Sample cup	Hitachi sample cup, Beckman 700 sample cup, TECO sample cup, German Labor, CA530, BECL4, BE cup, Coulter color dilution plate BS120, BS200, BS300
Urine/Stool container	30ml, 40ml, 60ml, 90ml, 100ml, 120ml, 150ml
Transfer pipette	10ul, 0.5ml, 1ml, 2ml, 3ml, 5ml, 10ml
Embedding cassette	Square holes, round holes, stripe holes, without cover
Microscope slide	7101, 7102, 7105, 7107, 7109
Cover glass	18x18mm, 20x20mm, 22x22mm, 24x24mm, 24x32mm, 24x50mm, 24x60mm
Microscope slide box	25place, 50place, 100place, paper and plastic
Glass test tube	10x75, 12x75, 12x100, 13x100, 15x100, 16x100, 16x150, 18x180, 20x150,



	20x200,25x200
Glass capillary tube	Blue glass capillary tube, red glass capillary tube
Beaker	25ml,50ml, 100ml, 250ml, 500ml, 1000ml
Measuring cylinder	10ml, 50ml, 100ml, 250ml, 500ml, 1000ml
Reagent bottle	4ml,6ml,8ml,15ml,20ml,30ml,50ml,90ml,100ml,125ml,500ml, 1000ml
Blood counting chamber	0.100mm
Vacuum blood collection tube	8x120mm,9x120mm,13x75mm,13x100mm,16x100mm
Esr tube	60mm, 210mm, 230mm
Pipette	0.1-2.5ul,0.5-10ul,2-20ul,5-50ul,10-100ul,20-200ul,50-200ul,100-1000ul,200-1000ul,1000-5000ul,2-10ml,0.1ul,0.2ul,0.25ul,0.5ul,1ul,2ul,2.5ul,5ul,10ul,20ul,25ul,50ul,100ul,200ul,250ul,500ul,1000ul,2000ul,2500ul,5000ul
Saliva sample collector	5/10mL
Tourniquet	45cm
Wooden stick	150mm
Esr detector	6holes, 10 holes
Glass flask	25ml,50ml,100ml,200ml,250ml,500ml,1000ml,2000ml,
Non vacuum tubes	12x55mm,16x55mm,13x75mm,13x100mm,16x100mm
Plastic rack/box	96well,60well,72well,32well,36well,40well,50well,81well,100well,48well,28well,90well,25well
Filter pipette tip	10ul, 20ul, 30ul, 50ul, 100ul, 150ul, 200ul, 300ul, 500ul,1000ul, 1250ul



Pcr tube	0.1ml, 0.2ml
Pcr plate	96well: full skirt, Semi-skirt, No skirt.
Pcr strip	4strips. 8strips. 12strips
Pcr film	SF-501 suit for 96-well pcr plate
Specimen collection swab	3cm, 8cm, 150mm
Transport swab	Stuart, amies, Cary blair
Sterile swab stick	12*175mm, 2.2x150mm
Cuvette	12.5*45mm
Deep Well Plate	96well
Tip Comb	8 strip
Serological Pipette	1ml, 2ml, 5ml, 10ml, 25ml, 50ml
Conductive Pipette Filter Tip	10ul 20ul 50ul 200ul 300ul 1000ul
Extraction tube	10ul 20ul 30ul 40ul 45ul 50ul 60ul 1ml 1.5ml 2ml 3ml 5ml 10ml

