



EC Declaration of Conformity



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

Applicant

Manufacturer: NANTONG TIANYE LABWARE CO., LTD.

Address: Sanhe Town, Haimen City, Jiangsu Province, China.

Product

Name: Centrifuge Tube, Centrifuge Tube Box, Cryovial Tube, Cryovial Tube Box, Pipette Tip, Pipette Tip Box, Test Tube, Test Tube Stopper, Test Tube Rack, Petri Dish, Tissue Culture Plate, Inoculation Loop, Sample Cup, Urine/Stool Container, Transfer Pipette, Embedding Cassette, Microscope Slide, Microscope Slide Box, Cover Glass, Glass Test Tube, Swab, Glass Capillary Tube

Type: See Annex of details

Classification: IVDD Other

We confirm our product can meet the requirement of In Vitro Diagnostic Medical Devices Directive (98/79EC) and the following harmonized standards.

- EN ISO 14971:2012
- EN ISO 18113-1:2011
- EN ISO 18113-3:2011



Date: 2017.12.10



ANNEX

Product Name	Type
Centrifuge Tube	0.2ml– 50ml
Centrifuge Tube Box	60well,96well,72well,32well,50well.
Cryovial Tube	0.5ml , 1ml, 1.5ml, 1.8ml, 4ml, 5ml
Cryovial Tube Box	50well, 81well, 96well, 100well
Pipette Tip	10ul, 200ul, 1000ul, 1250ul, 5ml,
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
Test Tube Rack	40well, 50well, 60well, 90well, multi functional
Petri Dish	35x15mm, 60x15mm, 70x15mm, 90x15mm, 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
Urine/Stool Container	30ml, 60ml, 100ml, 120ml
Transfer Pipette	10ul, 0.5ml, 1ml, 2ml, 3ml
Embedding Cassette	Square holes, round holes, stripe holes , without cover
Microscope Slide	7101, 7102, 7105, 7107, 7109
Microscope Slide Box	25place, 50place, 100place, paper and plastic
Cover Glass	18x18mm, 20x20mm, 22x22mm, 24x24mm, 24x32mm, 24x50mm, 24x60mm
Glass Test Tube	12x75, 12x100, 13x100, 15x100, 16x100, 16x150, 18x180, 20x150, 20x200, 25x200
Swab	Wood club, plastic club
Glass Capillary Tube	Blue glass capillary tube, red glass capillary tube



Signature