



Compliance Report

| Applicant: | NANTONG TIANYE LABWARE CO., LTD. |
|------------|---|
| Address: | Sanhe Town, Haimen City, Jiangsu Province, China. |
| | |

Product: Type: See Annex See Annex

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. **03267** Initial Issue Date: **20 July 2021**

Berry Bao

Signer



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Annex to Report (No. 03267)

NANTONG TIANYE LABWARE CO., LTD.

| Product Name | Туре | | |
|-----------------------|--|--|--|
| 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 | | |

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| Product Name | Туре |
|------------------------------|---|
| 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 |
| | 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 |
| Pipette | ,0.1ul,0.2ul,0.25ul,0.5ul,1ul,2ul,2.5ul,5ul,10ul,20ul, |
| | 25ul,50ul,100ul,200ul,250ul,500ul,1000ul,2000ul,250 |
| | 0ul,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,81 |
| | well,100well,48well,28well,90well,25well |
| Filter pipette tip | 10ul,20ul,30ul, 50ul, 100ul ,150ul, 200ul, 300ul ,500ul,1000ul, |
| | 1250ul |

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| Product Name | Туре |
|-------------------------------|--|
| 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 per 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 60ul1ml 1.5ml 2ml 3ml 5ml10ml |

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