

Compliance Report

Applicant:

Haimencity Kahotest Citotest Labware Manufacturing Co., Ltd.

Address:

NO, 3256 Dagang Road, Sanhe Town, Haimen City, Jiangsu

Province, China

Product:

Pipette Tip, Centrifuge Tube, Cryo Tube, Storage Box, Test Tube,

Test Tube Stopper, Test Tube Rack, Petri Dish, Culture Plate, Inoculation Loop, Transport Swab, Secretions Test Preprocessing

Device, Pasteur Pipette, Vacuum Blood Collection, Urine Container, Stool Container, Medicine Cup, Stool Test

Preprocessing Device, Embedding Cassette, Cabinet, Slide, Cover

Glass, Mailer For Slides

Type:

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. 03234

Initial Issue Date: 21 Sep 2020

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Signer

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The report information can be found on, WWW.SNOA.COM.CN.





Annex to Report (No. 03234)

Haimencity Kahotest Citotest Labware Manufacturing Co., Ltd.

| Product Name | Туре |
|--------------------------------------|--|
| Pipette Tip | 10ul/200ul/300ul/1000ul/5ml/10ml |
| Centrifuge Tube | 0.2ml/0.5ml/1.5ml/2ml/5ml/7ml/10ml/15ml/50ml/100ml |
| Cryo Tube | 0.5ml/1ml/1.5ml/1.8ml/2ml/5ml/10ml |
| Storage box | 10ul(96wells)/200ul(96wells)/1000ul(60wells, 100wells)/ |
| | 5ml(28wells)/ 10ml(15wells) |
| | 0.2ml(96wells, 100wells, 153wells)/0.5ml(72wells, |
| | 98wells)/1.5ml(72wells, 100wells)/5ml(32wells)/ |
| | 0.5ml and 1.5ml (60 wells, 96 wells) /0.2-50 ml/15ml/50 ml |
| | 16wells/36wells/49wells/81wells/100wells |
| Test Tube | 12X75MM/13X75MM/12X100MM/13X100MM/15X100MM/ |
| | 16X100MM/16X102MM/16X125MM/16X150MM/40X200MM |
| Test Tube Stopper | 12mm/13mm/16mm/40mm |
| Test Tube Rack | 40wells/50wells/60wells/90wells/66pillar |
| Petri Dish | 35mm/60mm/70mm/90mm/100mm/120mm/130mm/150mm |
| Culture Plate | 6wells/12wells/24wells/48wells/96wells/384wells |
| Inoculation Loop | 1ul/10ul/1+10ul |
| Transport Swab | 13X165mm |
| Secretions Test Preprocessing Device | JHD023 |
| Pasteur Pipette | 0.2ml/0.5ml/1ml/2ml/3ml/5ml/10ml |
| Vacuum Blood | 3ml/4ml/5ml/6ml/7ml/8ml/9ml |
| Collection | |
| Urine Container | 30ml/40ml/60ml/100ml/120ml |
| Stool Container | 5ml/15ml/30ml/40ml/60ml/100ml/120ml |
| Medicine Cup | 30ml |
| Stool Test Preprocessing Device | JHF012 |

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



Annex to Report (No. 03234)

Haimencity Kahotest Citotest Labware Manufacturing Co., Ltd.

| Product Name | Туре |
|--------------------|--|
| Embedding cassette | Square holes/stripe holes/round holes/fine square holes/O rings |
| Cabinet | JHG012/013/014/015 |
| Slide | 7101/7102/7105/7107/7108/7109/7110 |
| Cover Glass | 18*18mm/20*20mm/22*22mm/24*24mm/24*32mm/24*40mm/ 24*50mm/24*60mm |
| Mailer For Slides | 1 place/2 place/3 place/5place/10 place/12 place/20 place /25 place/50 place/100 place |

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