



# EC Declaration of Conformity

according to the Directive 98/79/EC  
(applicable to **Others/General IVD** Devices only)

**Manufacturer:** CITOTEST LABWARE MANUFACTURING CO., LTD  
48 Xinxiu Road, Haimen City 226100, Jiangsu, China

**Product/s:** **Microscope cover glasses**  
**Model:** Please Refer To Attached Chart III

**Category:** **Others/General**  
**Conformity assessment route:** **Annex III, except point 6, of Directive (Module A)**

**Applicable Standards:** **ISO8255-1-2011 (E)**      **ISO8255-2: 2013 (E)**  
**EN ISO15223-1:2012**      **EN 1041: 2008**  
**EN ISO14971:2012**

We, the Manufacturer, herewith declare with sole responsibility that our product/s mentioned above meet/s the provisions of the Directive 98/79/EC of the European Parliament and of the Council on In-Vitro Diagnostic Medical Devices.

We hereby explicitly appoint Wellkang Ltd t/a Wellkang Tech Consulting located at 29 Harley Street, London W1G 9QR, UK to act as our European Authorised Representative as defined in the aforementioned Directive.

Signed on   5  /(Day)   11  /(Month) of 2014. Place (Haimen), PR China

Represented by

Signature (on behalf of the manufacturer) Chen hai wei

Full Name of authorized signatory: 陈海卫  
Position held in the company: Quality Manager

Company Seal/Stamp:



## Attached Chart III

10221818C (0341-0130)	10222020C (0341-0630)	10222222C (0341-1130)
10222424C (0341-1630)	10222232C (0341-2710)	10222432C (0341-2810)
10222240C (0341-3110)	10222440C (0341-3210)	10222250C (0341-3510)
10222450C (0341-3610)	10222260C (0341-3910)	10222460C (0341-4010)
10211818C (0340-0130)	10212020C (0340-0630)	10212222C (0340-1130)
10212424C (0340-1630)	10212232C (0340-2710)	10212432C (0340-2810)
10212240C (0340-3110)	10212440C (0340-3210)	10212250C (0340-3510)
10212450C (0340-3610)	10212260C (0340-3910)	10212460C (0340-4010)
10231818C (0342-0130)	10232020C (0342-0630)	10232222C (0342-1130)
10232424C (0342-1630)	10232232C (0342-2710)	10232432C (0342-2810)
10232240C (0342-3110)	10232440C (0342-3210)	10232250C (0342-3510)
10232450C (0342-3610)	10232260C (0342-3910)	10232460C (0342-4010)
10201818 (0332-0130)	10202020 (0332-0630)	10202222 (0332-1130)
10202424 (0332-1630)	10202232 (0332-2710)	10202432 (0332-2810)
10202240 (0332-3110)	10202440 (0332-3210)	10202250 (0332-3510)
10202450 (0332-3610)	10202260 (0332-3910)	10202460 (0332-4010)
10101818 (0330-0130)	10102020 (0330-0630)	10102222 (0330-1130)
10102424 (0330-1630)	10102232 (0330-2710)	10102432 (0330-2810)
10102240 (0330-3110)	10102440 (0330-3210)	10102250 (0330-3510)
10102450 (0330-3610)	10102260 (0330-3910)	10102460 (0330-4010)
10151818 (0331-0130)	10152020 (0331-0630)	10152222 (0331-1130)
10152424 (0331-1630)	10152232 (0331-2710)	10152432 (0331-2810)
10152240 (0331-3110)	10152440 (0331-3210)	10152250 (0331-3510)
10152450 (0331-3610)	10152260 (0331-3910)	10152460 (0331-4010)
10231818CE (0342-0120)	10232020CE (0342-0620)	10232222CE (0342-1120)
10232424CE (0342-1620)	10232232CE (0342-2720)	10232432CE (0342-2820)
10232240CE (0342-3120)	10232440CE (0342-3220)	10232250CE (0342-3520)
10232450CE (0342-3620)	10232260CE (0342-3920)	10232460CE (0342-4020)
10211818CE (0340-0120)	10212020CE (0340-0620)	10212222CE (0340-1120)
10212424CE (0340-1620)	10212232CE (0340-2720)	10212432CE (0340-2820)
10212240CE (0340-3120)	10212440CE (0340-3220)	10212250CE (0340-3520)
10212450CE (0340-3620)	10212260CE (0340-3920)	10212460CE (0340-4020)
10221818CE (0341-0120)	10222020CE (0341-0620)	10222222CE (0341-1120)
10222424CE (0341-1620)	10222232CE (0341-2720)	10222432CE (0341-2820)
10222240CE (0341-3120)	10222440CE (0341-3220)	10222250CE (0341-3520)
10222450CE (0341-3620)	10222260CE (0341-3920)	10222460CE (0341-4020)
10210008CE (0344-0820)	10210010CE (0344-1020)	10210011CE (0344-1120)
10210012CE (0344-1220)	10210013CE (0344-1320)	10210014CE (0344-1420)
10210015CE (0344-1520)	10210016CE (0344-1620)	10210018CE (0344-1820)
10210020CE (0344-2020)	10210022CE (0344-2220)	10210024CE (0344-2420)
10210025CE (0344-2520)	10220008CE (0345-0820)	10220010CE (0345-1020)
10220011CE (0345-1120)	10220012CE (0345-1220)	10220013CE (0345-1320)
10220014CE (0345-1420)	10220015CE (0345-1520)	10220016CE (0345-1620)
10220018CE (0345-1820)	10220020CE (0345-2020)	10220022CE (0345-2220)
10220024CE (0345-2420)	10220025CE (0345-2520)	10230012CE (0346-1220)
10230008CE (0346-0820)	10230010CE (0346-1020)	10230011CE (0346-1120)
10230013CE (0346-1320)	10230014CE (0346-1420)	10230015CE (0346-1520)
10230016CE (0346-1620)	10230018CE (0346-1820)	10230020CE (0346-2020)
10230022CE (0346-2220)	10230024CE (0346-2420)	10230025CE (0346-2520)
10262026 (5850-0002)	10232026 (5850-0003)	10282026 (5850-0001)
10232222 (5850-0004)	10232424 (5850-0005)	0341-5010
0340-5010	0342-5010	0331-5010
0330-5010	0332-5010	0341-5020

0340-5020	0342-5020	10211818X(0340-0150)
10212020X(0340-0650)	10212222X(0340-1150)	10212424X(0340-1650)
10212232X(0340-2750)	10212432X(0340-2850)	10212240X(0340-3150)
10212440X(0340-3250)	10212250X(0340-3550)	10212450X(0340-3650)
10212260X(0340-3950)	10212460X(0340-4050)	0340-5050
10221818X(0341-0150)	10222020X(0341-0650)	10222222X(0341-1150)
10222424X(0341-1650)	10222232X(0341-2750)	10222432X(0341-2850)
10222440X(0341-3150)	10222440X(0341-3250)	10222250X(0341-3550)
10222450X(0341-3650)	10222260X(0341-3950)	10222460X(0341-4050)
0341-5050	10231818X(0342-0150)	10232020(0342-0650)
10232222X(0342-1150)	10232424X(0342-1650)	10232232X(0342-2750)
10232432X(0342-2850)	10232240X(0342-3150)	10232440X(0342-3250)
10232250X(0342-3550)	10232450X(0342-3650)	10232260X(0342-3950)
10232460X(0342-4050)	0342-5050	10101818X(0330-0150)
10102020X(0330-0650)	10102222X(0330-1150)	10102424X(0330-1650)
10102232X(0330-2750)	10102432X(0330-2850)	10102240X(0330-3150)
10102440X(0330-3250)	10102250X(0330-3550)	10102450X(0330-3650)
10102260X(0330-3950)	10102460X(0330-4050)	0330-5050
10151818X(0331-0150)	10152020X(0331-0650)	10152222X(0331-1150)
10152424X(0331-1650)	10152232X(0331-2750)	10152432X(0331-2850)
10152240X(0331-3150)	10152440X(0331-3250)	10152250X(0331-3550)
10152450X(0331-3650)	10152260X(0331-3950)	10152460X(0331-4050)
0331-5050	10201818X(0332-0150)	10202020X(0332-0650)
10202222X(0332-1150)	10202424X(0332-1650)	10202232X(0332-2750)
10202432X(0332-2850)	10202240X(0332-3150)	10202440X(0332-3250)
10202250X(0332-3550)	10202450X(0332-3650)	10202260X(0332-3950)
10202460X(0332-4050)	0332-5050	10101515(0330-5530)
10102126(0330-5630)		

Company Seal/Stamp:





# Atitikties deklaracija

pagal direktyvą 98/79/EC  
(taikomas tikslai Kitoms/Bendroms IVD priemonėms)

*Gamintojas:* CITOTEST LABWARE MANUFACTURING CO., LTD  
no 48, XinXiu Road Haimen City JiangSu Province 226100,  
PR China

*Produktas/ai:* Mikroskopiniai dengiamieji stikliukai  
*Modelis:* Žiūrėti sąrašą III

*Kategorija:* Kiti/Bendrieji  
*Atitikties įvertinimas:* III priedas, išskyrus 6 punktą, direktyva (Modulis A)

*Taikomi standartai:* ISO8255-1-2011 (E)      ISO8255-2: 2013 (E)  
EN ISO15223-1:2012      EN 1041: 2008  
EN ISO14971:2012

Mes, gamintojas, savo atsakomybe deklaruojame, kad aukščiau minimas produktas/ai atitinka Europos Parlamento ir Tarybos In-Vitro diagnostinių medicinos priemonių direktyvos 98/78/EC nuostatas.

Mes aiškiai įgaliojame Wellkang Ltd t/a Wellkang Tech Consulting įsikūrusią 29 Harley Steet, Londonas W1G 9QR, UK veikti kaip įgaliotą atstovą Europoje, kaip kad yra numatoma minimoje direktyvoje.

Pasirašyta 2014m.      Vieta (Haimen), PR Kinija

Atstovaujama

Parašas (gamintojo vardu)      */parašas/*

Įmonėje užimamos pareigos: Generalinis Direktorius

Įmonės štampas:



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(applicable to **Others/General IVD** Devices only)

*Manufacturer:* CITOTEST LABWARE MANUFACTURING CO., LTD  
48 Xinxu Road, Haimen City 226100, Jiangsu, China

*Product/s:* **Microscope slides**  
*Model:* Please Refer To Attached Chart I

*Category:* **Others/General**  
*Conformity assessment route:* **Annex III, except point 6, of Directive (Module A)**

*Applicable Standards:* **ISO8037/1-1986 (E)**      **ISO8037-2: 1997 (E)**  
**EN ISO 15223-1-2012**      **EN 1041: 2008**  
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We, the Manufacturer, herewith declare with sole responsibility that our product/s mentioned above meet/s the provisions of the Directive 98/79/EC of the European Parliament and of the Council on In-Vitro Diagnostic Medical Devices.

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Signed on 21 / (Day) 12 / (Month) of 2014. Place (Haimen), PR China

Represented by

Signature (on behalf of the manufacturer) 陈海卫

Full Name of authorized signatory: 陈海卫  
Position held in the company: Quality Manager

Company Seal/Stamp





# Atitikties deklaracija

pagal direktyvą 98/79/EC  
(taikomas tikslai Kitoms/Bendroms IVD priemonėms)

*Gamintojas:* CITOTEST LABWARE MANUFACTURING CO., LTD  
no 48, XinXiu Road Haimen City JiangSu Province 226100,  
PR China

*Produktas/ai:* Mikroskopiniai objektyviniai stikliukai  
*Modelis:* Žiūrėti sąrašą I

*Kategorija:* Kiti/Bendrieji  
*Atitikties įvertinimas:* III priedas, išskyrus 6 punktą, direktyva (Modulis A)

*Taikomi standartai:* ISO8037/1-1986 (E) ISO8037-2 1997 (E)  
EN ISO 15223-1-2012 EN 1041: 2008  
EN ISO14971:2012

Mes, gamintojas, savo atsakomybe deklaruojame, kad aukščiau minimas produktas/ai atitinka Europos Parlamento ir Tarybos In-Vitro diagnostinių medicinos priemonių direktyvos 98/78/EC nuostatas.

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Pasirašyta 2014 m. Vieta (Haimen), PR Kinija

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Įmonėje užimamos pareigos: Generalinis Direktorius

Įmonės štampos: