EU Declaration of Conformity

according to IVDR Regulation (EU) 2017/746

*(applicable to devices of **class A, Manufacturer's Self-Declaration**)*

Manufacturer: CITOTEST LABWARE MANUFACTURING CO., LTD

Address: No. 339 Beihai West Road
Haimen District, 226100 Jiangsu Province, P.R. China

Manufacturer's SRN: CN-MF-000017214

Manufacturer's authorised representative (EC Rep):
Wellkang Ltd (www.CE-marking.eu)
Enterprise Hub, NW Business Complex,
1 Beraghmore Rd., **Derry**, BT48 8SE, **Northern Ireland, UK.**
EC Rep's **SRN** in EUDAMED: **XI-AR-000001836.**

We, the manufacturer, declare under the sole responsibility of the manufacturer that

the medical device(s)	Product Name	Centrifuge Tube
	Model/code/Ref, (for identification/traceability)	Micro, Macro,5,10,12,15ml，50ml
	(If there are many products, use wording "please refer in attached list")	
Risk class	Class A No sterile	
covered by the present declaration is/are in conformity with the IVDR- Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on In Vitro Diagnostic medical devices and, if applicable, with any other relevant Union legislation.		
Notified Body (name & number), conformity assessment procedure, & **Certificate** no.	**NOT available**	
Basic UDI-DI	697079159CETA000A00NAU	
Common specification (CS)	**NOT applicable**	

Signed on: 15 Mar. 2022. Place: Haimen, Jiangsu, P.R. China

Signature (on behalf of the manufacturer) Zhang Dechao

Name of authorized signatory: Zhang Dechao

Position held in the company: Quality Manager

CITOTEST LABWARE MANUFACTURING CO., LTD

Digitally signed by Jighili Tatiana
Date: 2025.03.12 16:19:40 EET
Reason: MoldSign Signature
Location: Moldova
MOLDOVA EUROPEANĂ

Attached Chart I

4610-1850	4610-1856	4610-1877	4610-1878	4610-1801
4610-1802	4004-1101	4004-1102	4004-1103	4004-1104
4004-1105	4004-1006	4004-1007	4020-2501	4004-1114
4004-1115	4004-1108	4004-1109	4004-1110	4004-1111
4610-1842	4610-1845	4610-1822	4610-1816	4610-1817
4610-1815	4610-1862	4610-1903	4610-1843	4610-1863
4610-1901	4610-1823	4610-1824	4610-1825	4610-1826
4119-0010	4119-0028	4119-0030	4119-0050	4139-0010
4139-0016	4139-0030	4139-0050	4148-0015	4148-0035
4148-0050	4120-0250	4120-0500	4120-9500	4120-1000
4120-1010	4141-1006	4120-2006	4611-1252	4611-1271
4610-1819	4610-1820	4610-1821	5460-2001	5460-2002-13
5460-2003-08	5460-2004-17	5460-2005-02	5460-2006	5460-2007-13
5460-2008-08	5460-2009-17	5460-2010-02	5460-2011	5460-2005-02
4610-1942-02	4610-1923-02	4610-1923	4610-1942	4610-1982
4610-1907	4610-1642	4610-1983-02	4610-1985	

EU Declaration of Conformity

according to IVDR Regulation (EU) 2017/746

*(applicable to devices of **class A, Manufacturer's Self-Declaration**)*

Manufacturer: CITOTEST LABWARE MANUFACTURING CO., LTD

Address: No. 339 Beihai West Road
Haimen District, 226100 Jiangsu Province, P.R. China

Manufacturer's SRN: CN-MF-000017214

Manufacturer's authorised representative (EC Rep):
Wellkang Ltd (www.CE-marking.eu)
Enterprise Hub, NW Business Complex,
1 Beraghmore Rd., **Derry**, BT48 8SE, **Northern Ireland, UK**.
EC Rep's **SRN** in EUDAMED: **XI-AR-000001836.**

We, the manufacturer, declare under the sole responsibility of the manufacturer that

the medical device(s)	Product Name	Test Tube
	Model/code/Ref, (for identification/traceability)	Plastic, Glass
	(If there are many products, use wording "please refer in attached list")	
Risk class	Class A No sterile	
covered by the present declaration is/are in conformity with the IVDR- Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on In Vitro Diagnostic medical devices and, if applicable, with any other relevant Union legislation.		
Notified Body (name & number), conformity assessment procedure, & **Certificate** no.	**NOT available**	
Basic UDI-DI	**697079159ASCA000A00N9D**	
Common specification (CS)	**NOT applicable**	

Signed on: 22 Mar. 2022. Place: Haimen, Jiangsu, P.R. China

Signature (on behalf of the manufacturer) Zhang Dechao

Name of authorized signatory: Zhang Dechao

Position held in the company: Quality Manager

Attachments-Doc IVDR-ID#TCF-IVDR-021,VA/00-04/26/2022

Attached Chart I

4004-0213	4004-0133	4004-0231	4004-0333	4004-0507
4004-0101	4004-0134	4004-0232	4004-0401	4004-0508
4004-0102	4004-0135	4004-0233	4004-0402	4004-0509
4004-0103	4004-0136	4004-0301	4004-0403	4004-0510
4004-0104	4004-0137	4004-0302	4004-0404	4004-0511
4004-0105	4004-0138	4004-0303	4004-0405	4004-0512
4004-0106	4004-0140	4004-0304	4004-0406	4004-0513
4004-0107	4004-0201	4004-0305	4004-0407	4004-0514
4004-0108	4004-0202	4004-0306	4004-0408	4004-0515
4004-0109	4004-0203	4004-0307	4004-0409	4004-0516
4004-0110	4004-0204	4004-0308	4004-0410	4004-0517
4004-0111	4004-0205	4004-0309	4004-0411	4004-0518
4004-0114	4004-0206	4004-0310	4004-0412	4004-0519
4004-0112	4004-0207	4004-0311	4004-0413	4004-0520
4004-0113	4004-0208	4004-0312	4004-0414	4004-0521
4004-0115	4004-0209	4004-0313	4004-0415	4004-0522
4004-0116	4004-0210	4004-0314	4004-0416	4004-0523
4004-0117	4004-0211	4004-0315	4004-0417	4004-0524
4004-0118	4004-0212	4004-0316	4004-0418	4004-0525
4004-0119	4004-0214	4004-0317	4004-0419	4004-0526
4004-0120	4004-0215	4004-0318	4004-0420	4004-0601
4004-0121	4004-0216	4004-0319	4004-0421	4004-0603
4004-0122	4004-0217	4004-0319	4004-0422	4004-0605
4004-0123	4004-0218	4004-0320	4004-0423	4004-0719
4004-0124	4004-0219	4004-0321	4004-0424	4004-0720
4004-0125	4004-0220	4004-0322	4004-0425	4004-0721
4004-0126	4004-0221	4004-0323	4004-0426	4004-0801
4004-0127	4004-0222	4004-0324	4004-0501	4004-0802
4004-0128	4004-0223	4004-0325	4004-0502	4004-0803
4004-0129	4004-0224	4004-0326	4004-0503	4004-0804
4004-0130	4004-0225	4004-0330	4004-0504	4004-0805
4004-0131	4004-0226	4004-0331	4004-0505	4004-0806
4004-0132	4004-0230	4004-0332	4004-0506	4004-0807

4004-0808	4004-1013	4004-1301	4004-1003	4004-1106
4004-0809	4004-1014	4004-1302	4004-1004	4004-1107
4004-0810	4004-1015	4004-1303	4004-1005	4004-1108
4004-0811	4004-1016	4004-1304	4004-1006	4004-1109
4004-0812	4004-1017	4004-1305	4004-1007	4004-1110
4004-0813	4004-1018	4004-1306	4004-1008	4004-1111
4004-0814	4004-1019	4004-1307	4004-1009	4004-1112
4004-0815	4004-1020	4004-1308	4004-1010	4004-1113
4004-0816	4004-1021	4004-1309	4004-1011	4004-1114
4004-0817	4004-1022	4004-1310	4004-1012	4004-1115
4004-0818	4004-1023	4004-1401	4004-0808	4004-1013
4004-0819	4004-1024	4004-1402	4004-1101	4004-1504
4004-0820	4004-1025	4004-1403	4004-1102	4004-1601
4004-0901	4004-1026	4004-1404	4004-1103	4004-1602
4004-0902	4004-1027	4004-1408	4004-1104	44004-0507
4004-0903	4004-1028	4004-1501	4004-1105	44004-0525
4004-0904	4004-1029	4004-1502	4004-1001	4004-0907
4004-0905	4004-1030	4004-1503	4004-1002	4004-0908
4004-0906	4004-1514	4004-1515	4004-1512	4004-1513
4004-1618				

CE

EC Declaration of Conformity

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

Manufacturer: CITOTEST LABWARE MANUFACTURING CO., LTD
No .339 Beihai West Road, Haimen, 226100 Jiangsu,
P.R. China

Product/s: **Centrifuge Tubes**
Model: Please Refer To Attached Chart V III

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

Applicable Standards: **EN ISO15223-1:2016** **EN 1041：2016**
EN ISO14971:2019

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, Enterprise Hub, NW Business Complex,1 Beraghmore Rd., Derry, BT48 8SE, Northern Ireland, to act as our European Authorised Representative as defined in the aforementioned Directive.

Signed on __10__ /(Day)__03__/(Month) of 2022. Place (Haimen), PR China

Represented by

Signature (on behalf of the manufacturer) Zhang Dechao

Full Name of authorized signatory: Zhang Dechao
Position held in the company: Quality Manager

Company Seal/Stamp:

Attached Chart Ⅷ

4610-1904	4610-1924	4610-1941
4610-1908	4610-1924-02	4610-1941-02
4610-1921	4610-1925	4610-1943
4610-1922	4610-1940	4610-1943-02
4610-1922-02	4610-1940-02	4610-1943-13
4610-1981	4610-1984-02	4610-1891
4610-1887	4610-1888	4610-1844
4610-1883	4610-1910	4610-1911

Company Seal/Stamp:

CE

EC Declaration of Conformity

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

Manufacturer: CITOTEST LABWARE MANUFACTURING CO., LTD
No .339 Beihai West Road, Haimen, 226100 Jiangsu,
P.R. China

Product/s: **Pipette Tips**
Model: Please Refer To Attached Chart XII

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

Applicable Standards: **EN ISO15223-1:2016** **EN 1041：2016**
EN ISO14971:2019

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, Enterprise Hub, NW Business Complex,1 Beraghmore Rd., Derry, BT48 8SE, Northern Ireland, to act as our European Authorised Representative as defined in the aforementioned Directive.

Signed on _01__ /(Day)__01___ /(Month) of 2022. Place (Haimen), PR China

Represented by

Signature (on behalf of the manufacturer) Zhang Dechao

Full Name of authorized signatory: Zhang Dechao
Position held in the company: Quality Manager

CITOTEST LABWARE MANUFACTURING CO., LTD

Attached Chart XII

4330-0005-02	4330-0081	4330-1141	4330-3133	4330-6133
4330-0006-02	4330-0133	4330-1144	4330-3136	4330-6136
4330-0008-02	4330-0136	4330-1150	4330-3139	4330-6144
4330-0009-02	4330-0144-17	4330-1152	4330-3141	4330-6144-17
4330-0014-17	4330-0147	4330-2133	4330-3144	4330-6147
4330-0015-17	4330-0152-02	4330-2136	4330-3150	4330-6152-02
4330-0017-17	4330-0155	4330-2144-17	4330-3152	4330-6155
4330-0018-17	4330-1133	4330-2147	4330-5136	4330-6162
4330-0079	4330-1136	4330-2152-02	4330-5144	4330-6163-02
4330-0080	4330-1139	4330-2155	4330-5152	4330-7133
4330-7134	4330-7141	4330-7152	4330-8133	4330-8152
4330-7136	4330-7142	4330-7152-02	4330-8136	4330-8152-02
4330-7138	4330-7144	4330-7155	4330-8144	4330-8155
4330-7139	4330-7147	4330-7162	4330-8144-17	4330-8162
4330-7140	4330-7151	4330-7163	4330-8147	4330-9133
4330-9134	4330-9139	4330-9142	4330-9151	4330-9162
4330-9136	4330-9140	4330-9144	4330-9152	4330-9163
4330-9138	4330-9141	4330-9147	4330-9155	

Company Seal/Stamp:

CE

EC Declaration of Conformity

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

Manufacturer: CITOTEST LABWARE MANUFACTURING CO.，LTD
No.339 Beihai West Road, Haimen, 226100 Jiangsu, P.R. China

Product/s: **Test Tubes**

Model: Please Refer To Attached Chart **X**

Category: **Others/General**

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

Applicable Standards: **EN ISO15223-1:2016** **EN 20417:2021**
EN ISO14971:2019

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, Enterprise Hub, NW Business Complex,1 Beraghmore Rd., Derry, BT48 8SE, Northern Ireland, to act as our European Authorised Representative as defined in the aforementioned Directive.

Signed on _01_ /(Day)_04_/(Month) of 2022. Place (Haimen), PR China

Represented by

Signature (on behalf of the manufacturer) Zhang Dechao

Full Name of authorized signatory: Zhang Dechao
Position held in the company: Quality Manager

Company Seal/Stamp:

Attached Chart X

4004-0823	4004-1005	4004-1021
4004-0913	4004-1006	4004-1022
4004-1406	4004-1007	4004-1023
2308-6001	4004-1008	4004-1024
2308-6002	4004-1009	4004-1025
2308-6003	4004-1010	4004-1026
4004-1001	4004-1011	4004-1027
4004-1002	4004-1012	4004-1028
4004-1003	4004-1019	4004-1029
4004-1004	4004-1020	4004-1030
4004-1034	4004-1035	4004-1036
4004-1043	4004-1066	4004-1118
4004-1594-02	4004-1594-16	4004-1595-02
4004-1595-16	4004-1596-02	4004-1597-02
4004-1596-16	4004-1597-16	4004-1803
4004-1804	4004-1835	4004-1836

Company Seal/Stamp:

V6.9a

CE

EC Declaration of Conformity

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

Manufacturer: CITOTEST LABWARE MANUFACTURING CO.，LTD
No .339 Beihai West Road, Haimen, 226100 Jiangsu,
P.R. China

Product/s: **Transfer pipette(Pasteur pipettes)**
Model: Please Refer To Attached Chart Ⅳ

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

Applicable Standards: **EN ISO15223-1:2016** **EN 1041：2016**
EN ISO14971:2019

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, Enterprise Hub, NW Business Complex,1 Beraghmore Rd., Derry, BT48 8SE, Northern Ireland, to act as our European Authorised Representative as defined in the aforementioned Directive.

Signed on __01__ /(Day)__04___/(Month) of 2022. Place (Haimen), PR China

Represented by

Signature (on behalf of the manufacturer) Zhang Dechao

Full Name of authorized signatory: Zhang Dechao
Position held in the company: Quality Manager

Company Seal/Stamp:

Attached Chart Ⅳ

4320-0112	4320-0216	4320-0414	4320-0521	4320-0703
4320-0113	4320-0312	4320-0415	4320-0524	4320-0704
4320-0114	4320-0313	4320-0416	4320-0525	4320-0705
4320-0115	4320-0314	4320-0432	4320-0559	4320-0802
4320-0116	4320-0315	4320-0435	4320-0612	4320-0803
4320-0159	4320-0316	4320-0512	4320-0613	4320-0804
4320-0212	4320-0332	4320-0513	4320-0614	4320-0805
4320-0213	4320-0335	4320-0514	4320-0615	4320-0902
4320-0214	4320-0412	4320-0515	4320-0616	4320-0904
4320-0215	4320-0413	4320-0516	4320-0702	4320-0905
4320-1002	4320-1106	4320-1306	4320-1504	4320-1705
4320-1003	4320-1202	4320-1402	4320-1505	4320-1706
4320-1004	4320-1203	4320-1403	4320-1506	4320-1802
4320-1005	4320-1204	4320-1404	4320-1602	4320-1804
4320-1006	4320-1205	4320-1405	4320-1603	4320-1805
4320-1062	4320-1206	4320-1406	4320-1604	4320-1861
4320-1102	4320-1302	4320-1422	4320-1605	4320-1902
4320-1103	4320-1303	4320-1425	4320-1702	4320-1904
4320-1104	4320-1304	4320-1502	4320-1703	4320-1905
4320-1105	4320-1305	4320-1503	4320-1704	4320-2202
4320-2203	4320-2303	4320-2403	4320-2503	4320-2603
4320-2204	4320-2304	4320-2404	4320-2504	4320-2604
4320-2205	4320-2305	4320-2405	4320-2505	4320-2605
4320-2206	4320-2306	4320-2406	4320-2506	4320-2606
4320-2302	4320-2402	4320-2502	4320-2602	4320-2622
4320-2603	4320-2705	4320-3113	4320-3115	4320-3664
4320-2604	4320-3112	4320-3114	4320-3116	4320-3902
4320-0513				

Company Seal/Stamp:

EU Declaration of Conformity

according to MDR Regulation (EU) 2017/745

(applicable to devices of class I, Manufacturer's Self-Declaration)

Manufacturer: CITOTEST LABWARE MANUFACTURING CO., LTD

Address: No. 339 Beihai West Road
Haimen District, 226100 Jiangsu Province, P.R. China

Manufacturer's SRN: CN-MF-000017214

Manufacturer's authorised representative (EC Rep):
Wellkang Ltd (www.CE-marking.eu)
Enterprise Hub, NW Business Complex,
1 Beraghmore Rd., **Derry**, BT48 8SE, **Northern Ireland, UK**.
EC Rep's **SRN** in EUDAMED: **XI-AR-000001836.**

We, the manufacturer, declare under the sole responsibility of the manufacturer that

the medical device(s)	Product Name	Specimen Bag
	Model/code/Ref, (for identification/traceability)	LDPE
	(If there are many products, use wording "please refer in attached list")	
Risk class	Class I	
covered by the present declaration is/are in conformity with the MDR- Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices and, if applicable, with any other relevant Union legislation.		
Notified Body (name & number), conformity assessment procedure, & **Certificate** no.	**NOT available**	
Basic UDI-DI	**697079159SCDA300A00NEM**	
Common specification (CS)	**NOT applicable**	

Signed on: 07-25-2023 Place: Haimen, Jiangsu, P.R. China

Signature (on behalf of the manufacturer) Zhang Dechao

Name of authorized signatory: Zhang Dechao

Position held in the company: Quality Manager

Attached Chart I

0000-1001	0000-0021	0000-3001	0000-3002	0000-3003
0000-3004	0000-4001	0000-4002		