



EU Declaration of Conformity



according to IVDR Regulation (EU) 2017/746
(applicable to devices of class A, *Manufacturer's Self-Declaration*)

Manufacturer:
Address:

CITOTEST LABWARE MANUFACTURING CO., LTD
No. 339 Beihai West Road
Haimen District, 226100 Jiangsu Province, P.R. China
CN-MF-000017214

Manufacturer's SRN:

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	Microscope Slides
	Model/code/Ref, (for identification/traceability)	Plain, Frosted, Color, LBC and Smear
	(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	697079159MCSA000A00NHZ	
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



Attached Chart I

0317-0001	0317-0021	0307-0002	0307-0022	0307-0005
0307-0025	0313-0001	0313-0021	0303-0002	0303-0022
0303-0005	0303-0025	0312-0001	0312-0021	0302-0002
0302-0022	0302-0005	0302-0025	0314-0001	0314-0021
0304-0002	0304-0022	0317-2101	0317-2121	0307-2102
0307-2122	0307-2105	0307-2125	0313-2101	0313-2121
0303-2102	0303-2122	0303-2105	0303-2125	0312-2101
0312-2121	0302-2102	0302-2122	0302-2105	0302-2125
0314-2101	0314-2121	0304-2102	0307-2122	0317-2201
0317-2221	0307-2202	0307-2222	0307-2205	0307-2225
0313-2201	0313-2221	0303-2202	0303-2222	0303-2205
0303-2225	0312-2201	0312-2221	0302-2202	0302-2222
0302-2205	0302-2225	0314-2201	0314-2221	0304-2202
0304-2222	0317-6101-02	0317-6101-08	0317-6101-09	0317-6101-10
0317-6101-12	0317-6101-15	0317-6101-16	0317-6101-17	0307-6101-02
0307-6101-08	0307-6101-09	0307-6101-10	0307-6101-12	0307-6101-15
0307-6101-16	0307-6101-17	0313-6101-02	0313-6101-08	0313-6101-09
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0312-6101-17	0302-6101-02	0302-6101-08	0302-6101-09	0302-6101-10
0302-6101-12	0302-6101-15	0302-6101-16	0302-6101-17	0314-6101-02
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0317-6121-02	0317-6121-08	0317-6121-09	0317-6121-10	0317-6121-12
0317-6121-15	0317-6121-16	0317-6121-17	0307-6121-02	0307-6121-08
0307-6121-09	0307-6121-10	0307-6121-12	0307-6121-15	0307-6121-16
0307-6121-17	0313-6121-02	0313-6121-08	0313-6121-09	0313-6121-10
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0303-6121-08	0303-6121-09	0303-6121-10	0303-6121-12	0303-6121-15
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5860-0002	5860-0102	5860-0117	5860-0016	5860-0116
5860-0011	5860-0111	5860-0018	5860-0118	5814-0001
5860-0012	5860-0112	5814-0002	5860-0046	5860-0146
5860-0045	5860-0145	5860-0046	0385-0000-02	0385-0001-17
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2230-0202	2230-5000-02	2230-6000-02	2230-5000-13	2230-6000-13
2230-5000-08	2230-0203	2230-6000-08	2230-5000-17	2230-6000-17
2230-0103	0382-0001-13	0382-0001-16	0382-0002-13	0382-0002-02
0382-0002-01	0382-0001-02	0382-0001-08	2230-0001	2230-0002
2230-0003	0350-0063	0350-0064	0350-0065	0350-0030



0350-0031	0350-0033	0350-0032	0350-1002	0303-3102-02
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