



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	Pipette Tip
	Model/code/Ref, (for identification/traceability)	Regular, Filter
	(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	697079159PPTA000A00NZE	
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

4330-0016-17	4330-0017-17	4330-0018-17	4330-6136	4330-8035
4330-0013-17	4330-0014-17	4330-0015-17	4330-8043-17	4330-6043-17
4330-0019	4330-0020	4330-0024	4330-6046	4330-8144-17
4330-0023	4330-0022	4330-0025	4330-8147	4330-6147
4330-0021-17	4330-0012-02	4330-0004-02	4330-8052-02	4330-8051-02
4330-0005-02	4330-0006-02	4330-0007-02	4330-7034	4330-8152-02
4330-0008-02	4330-0009-02	4330-0010	4330-7139	4330-7136
4330-0011-02	4330-0001	4330-0003	4330-9141	4330-7141
4330-0032	4330-2032	4330-0033	4330-9144	4330-7144
4330-2033	4330-2058	4330-0035	4330-9152	4330-7152
4330-0058	4330-0036	4330-2036	4380-3109	4380-3106
4330-2035	4330-0043-17	4330-0037	4330-6035	4380-3111
4330-2037	4330-2044-17	4330-2043-17	4330-8136	4330-1057
4330-0044-17	4330-0045-17	4330-2045-17	4330-6144-17	4330-3038
4330-0046	4330-2046	4330-0047	4330-8046	4330-1040
4330-2047	4330-2048	4330-0051-02	4330-6051-02	4330-3049
4330-0048	4330-0052-02	4330-2052-02	4330-6152-02	4330-1051
4330-2051-02	4330-0054	4330-0053-02	4330-7136	4330-3057
4330-2053-02	4330-2055	4330-2054	4330-9139	4330-1034
4330-0055	4330-0056	4330-3042	4330-7042	4330-3040
4330-1038	4330-3042	4330-3042	4330-7051	4330-1042
4330-1049	4380-3108	4330-9155	4330-3051	

