



Declaration of Conformity

According to annex III of the Council Directive 98/79/EC on in vitro diagnostic medical device
We,

Manufacturer: CITOTEST LABWARE MANUFACTURING CO., LTD

Registered Address : 339 Beihai West Road, Haimen, Jiangsu, China

Declare under our sole responsibility that the following in vitro diagnostic medical devices
other than those covered by annex II and devices for performance evaluation

Name: Collection and Transport Kit

Type or model: VTM; VTM-N; ITM; PBS; NSS

Meet the provisions of the Council Directive 98/79/EC concerning medical devices which
apply to them.

Undersigned declares to fulfill the obligations imposed by Annex III section 2 to 5:

- availability of the technical documentation set in Annex III (section 3), allowing the assessment of conformity of the product with the requirements of the Directive.
- the manufacturer shall take necessary measures to ensure that the manufacturing process follows the principles of quality assurance as appropriate for the products manufactured (Annex III section 4).
- the manufacturer shall institute and keep up to date a systematic procedure to review experience gained from devices in the post-production phase and to implement appropriate means to apply any necessary corrective actions (Annex III section 5).

Conformity assessment was performed according to Article 9 (7) and Annex III, section 3.

Our current Quality System is formatted to international standards:

EN ISO 13485:2016 N ISO15223-1:2016 EN 1041:2008 EN ISO14971:2012
EN ISO 18113:1-2011 EN ISO 18113:2-2011 EN 13612:2002 EN ISO 23640:2015

Corporate Contact Information



COMMERCIAL CENTER&R-D Center
#1002, Building 3, 89 Shengli Rd, Jiangning
District, Nanjing 211106, China
Tel.: 0086 25 86216803
Fax: 0086 25 86214463
E-mail: info@citotest.com

PRODUCTION
339 Beihai West Road, Haimen, Jiangsu, China
Tel.: 0086 513 82259348
Fax: 0086 513 82110195
E-mail: info@citotest.com.cn



CITOTEST LABWARE MANUFACTURING CO.,LTD

www.citotest.com

MANU

CITOTEST LABWARE FACTURING CO., LTD

Registered Address : 339 Beihai West Road, Haimen, Jiangsu, China

Phone: 0086 513 82259348

Fax: 0086 513 82110195

Mail: zhangdechao@citotest.com.cn

Representative: Zhang Dechao

Position: Manager

Signature: *Zhang Dechao*

Date: *2020.12.8*

Stamp:



European Authorized Representative:

Registered Address:

Obelis s.a.

Bd. Général Wahis 53

B-1030 Brussels, Belgium

Phone: 32.2.732.59.54

Fax: 32.2.732.60.03

E-mail: mail@obelis.net

Representative: Mr. Gideon ELKAYAM (CEO)

Amies:

*2118-0406	*2118-0407	*2118-0018	*2118-0007
2118-0045			

Stuart:

*2118-0408	*2118-0409		
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VTM:

*2118-0412	*2118-0413	*2118-0413-99	*2118-0419-88
*2118-0419-99	*2118-0420	*2118-0420-99	*2118-0421
*2118-0421-88	*2118-0421-99	*2118-0422	*2118-0422-88
*2118-0422-99	2118-0010	2118-0019	2118-0012
2118-0013	*2118-1501	*2118-1502	*2118-1503
*2118-1504	*2118-1504-99	*2118-1509	*2118-1509-99
*2118-1511	*2118-1513-99	*2118-1521	*2118-1521-99
*2118-1522	*2118-1522-99	*2118-1523	*2118-1524
*2118-1531	*2118-1532	*2118-1533	*2118-1534
*2118-1541	*2118-1541-99	*2118-1542	*2118-1542-99
2118-0011	2118-0412-99	2118-1524-99	2118-1534-88
2118-1504-88	2118-1534-99	2118-0044	2118-1501-99
2118-1567-99			

VTM-N:

*2118-0414	*2118-0415	*2118-0416	*2118-0417
*2118-0417-88	*2118-0417-99	*2118-0423	*2118-0423-88
*2118-0424	*2118-0424-88	2118-0014	2118-0015
2118-0016	2118-0017	*2118-1505	*2118-1506
*2118-1507	*2118-1508	*2118-1510	*2118-1512
*2118-1525	*2118-1526	*2118-1527	*2118-1528
*2118-1528-99	*2118-1535	*2118-1536	*2118-1537
*2118-1538	2118-1508-99	2118-0042	2118-1538-88
2118-1544-99			

Note: the model with * in which the transport medium is applicable to the declaration of conformity

