

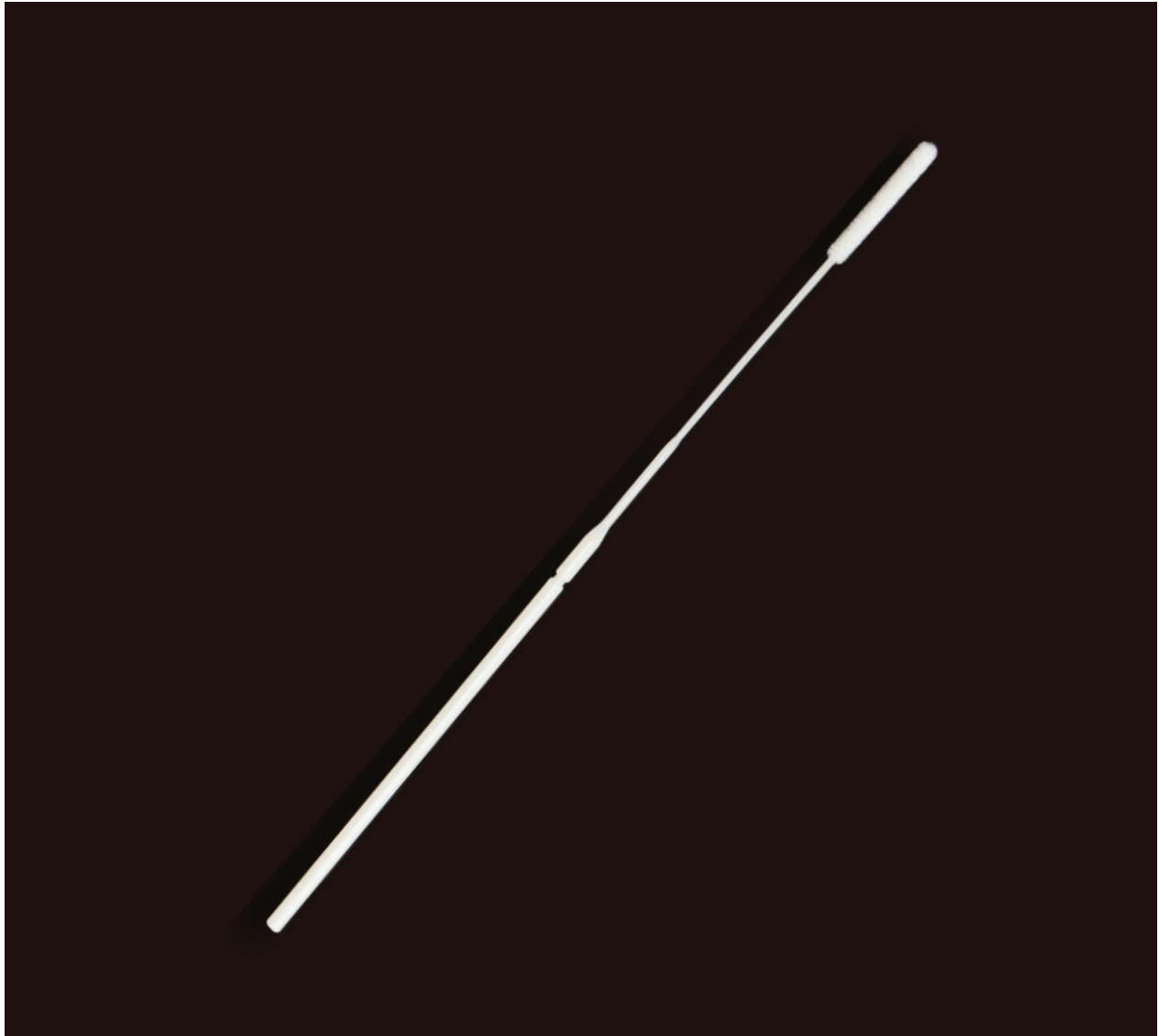
Abstrichtupfer

FÜR DIE ENTNAHME KLINISCHER MIKROBIOLOGISCHER PROBEN,
EINSCHLISSLICH BAKTERIEN, PILZE, VIREN, USW.

Handelsname: Collection Swabs

Hersteller: CITOTEST Labware Manufacturing Co., Ltd.

Abstrichtupfer



Abstrichtupfer
Konformitätserklärung

EC DECLARATION OF CONFORMITY
Document number / version : ST015-00

Name and address of the manufacturer:

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

We declare under our sole responsibility that
the medical device:

Collection Swabs
Type: See Attached Chart I

of class:

Ila

according to annex IX of directive 93/42/EEC /

meets the provisions of the directive 93/42/EEC and its transpositions in national laws which apply to it. The declaration
is valid in connection with the "final inspection report" of the device./

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.

Conformity assessment procedure: /

Directive 93/42/EEC Annex V,

Registration No.:

DD 2029176-1

Notified Body: /

TÜV Rheinland LGA Products GmbH
Tillystraße 2
90431 Nürnberg
Deutschland
CE 0197

HAIMEN 2021.04.01
Place, date



ZHANGDECHAO (QUALITY MANAGER)
Name and function

Zhang Dechao



Attached Chart I

2122-0009	2122-0010	2120-0024	2120-0025	2120-0026
2120-0027	2120-0028	2120-0029	2120-0020	2120-1203
2120-0521	2120-0503	2120-0621	2120-0603	2120-1101
2120-1103	2120-0030	2119-0433-13	2119-0501-02	2119-0601-02
2119-0431-02	2119-0531-02	2119-0631-02	2119-0502-01	2119-0602-01
2119-0432-01	2119-0532-01	2119-0632-01	2119-0504-16	2119-0604-16
2119-0434-16	2119-0534-16	2119-0634-16	2119-0505-15	2119-0605-15
2119-0435-15	2119-0535-15	2119-0635-15	2119-1101-02	2119-1102-01
2119-1104-16	2119-1105-15	2119-1131-02	2119-1132-01	2119-1134-16
2119-1135-15	2123-1003	2123-1006	2123-1009	2123-1017
2120-1521	2123-1035	2118-1809-88	2118-1851-99	2118-1852-99
2118-0407	2120-0023	2118-1563-99	2123-1017	2123-1020
2123-1023	2123-1029			



Abstrichtupfer CE Zertifikat

EC Certificate



**Production Quality Assurance
Directive 93/42/EEC on Medical Devices, Annex V**

Registration No.: DD 2029176-1

Manufacturer: CITOTEST Labware Manufacturing Co., Ltd.
No.339 Beihai West Road,
Haimen,
226100 Jiangsu
P.R. China

Products: Collection Swabs, Blood Lancets, Scalpel Blades, Cervical Brushes,
Cervical Scrapers;

For the following medical devices the scope covers only the aspects of
manufacture concerned with securing and maintaining sterile conditions:
Cotton Swabs, Wooden Tongue Depressors, Vaginal Speculums

The Notified Body hereby declares that the requirements of Annex V of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex V, section 4 of the aforementioned directive. For placing on the market of class IIb and class III devices covered by this certificate an EC type-examination certificate according to Annex III is required.

Report No.: 15053823 013
Effective date: 2021-03-16
Expiry date: 2022-10-23
Issue date: 2021-03-16



Fuxiu Sheng
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.

Page 1 of 2

EC Certificate



Production Quality Assurance
Directive 93/42/EEC on Medical Devices, Annex V

Registration No.: DD 2029176-1

Manufacturer: CITOTEST Labware Manufacturing Co., Ltd.
No.339 Beihai West Road,
Haimen,
226100 Jiangsu
P.R. China

The scope of certification includes the following manufacturing sites:

No.	Location	Product groups manufactured
/01	CITOTEST Labware Manufacturing Co., Ltd. No.48, Xinxiu Road, Haimen City, 226100 Jiangsu P.R. China	Collection Swabs, Cotton Swabs, Cervical Brushes

Report No.: 15053823 013
Effective date: 2021-03-16
Expiry date: 2022-10-23
Issue date: 2021-03-16



Fuxiu Sheng
TÜV Rheinland LGA Products GmbH
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Page 2 of 2

Business Stream Products
Certification Department



Precisely Right.

TÜV Rheinland LGA Products GmbH • 51105 Köln

CITOTEST Labware Manufacturing Co., Ltd.
No.339 Beihai West Road,
Haimen,
226100 Jiangsu
P.R. China

Contact

Tel. +49 911 655-5225
Mail: medical-products@de.tuv.com

Date December 09, 2021

Application for: QMS

Certificate No. : DD 2029176-1
Requirement : Richtlinie 93/42/EWG
Confirmation letter ID : 2021-03-16_DD 2029176-1 (The report number was mistakenly indicated as 15053823 013 in the certificate DD 2029176-1 issued on 2021-03-16, which should be 24431817-200)
Report no. : 244345961-200

Dear Madame or Sir,

Update of information to Certificate no. DD 2029176-1, issued on 03.12.2021

The change notification received on 21.06.2021 related to the information stipulated on the above mentioned certificate was assessed and information confirmed.

We confirm that the change notification is not considered a significant change in design or intended purpose under Regulation (EU) 2017/745 on medical devices (MDR), Article 120(3).

With this document we would like to confirm the following updated information to the afore mentioned certificate

TÜV Rheinland
LGA Products GmbH

Am Grauen Stein
51105 Köln
Germany

Headquarter

Tillystraße 2
90431 Nuremberg

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Fax +49 911 655 5226
service@de.tuv.com
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Board of Management

Dipl.-Ing.
Jörg Mähler, Spokesman

Dipl.-Kfm.
Dr. Jörg Schlösser

Nuremberg HRB 26013
VAT No.: DE 811835490

Chairman of the
Supervisory Board

Dipl.-Ing. Ralf Scheller

Revised Product name(s)

Old product designation: Collection Swabs, Blood Lancets, Scalpel Blades, Cervical Brushes, Cervical Scrapers;

For the following medical devices the scope covers only the aspects of manufacture concerned with securing and maintaining sterile conditions: Cotton Swabs, Wooden Tongue Depressors, Vaginal Speculums

New product designation: Collection Swabs, Cervical Brushes;

For the following medical devices the scope covers only the aspects of manufacture concerned with securing and maintaining sterile conditions: Cotton Swabs

Best regards,



Fuxiu Sheng

Certification body