

Certificate



Quality Management System
EN ISO 13485:2016

Registration No.: SX 2029176-1

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

Scope: Manufacture and Distribution of Disposable Medical Labware and
Instruments, Collection Swabs, Cervical Brushes, Cotton Swabs

A large, light-colored watermark of the TÜVRheinland logo is centered on the page. It consists of a stylized triangle with a horizontal bar inside, and the text 'TÜVRheinland' with a registered trademark symbol below it.

TÜVRheinland

The Certification Body of TÜV Rheinland LGA Products GmbH certifies that the organization has established and applies a quality management system for medical devices. Proof has been furnished that the requirements specified in the abovementioned standard are fulfilled. The quality management system is subject to yearly surveillance.

Report No.: 244345961-200
Effective date: 2021-12-03
Expiry date: 2023-10-23
Issue date: 2021-12-03



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

Certificate



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EN ISO 13485:2016**

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The scope of certification also covers the following:

No.	Facility	Scope
/01	c/o CITOTEST Labware Manufacturing Co., Ltd. No.48, Xinxiu Road, Haimen City, 226100 Jiangsu P.R. China	Manufacture of Disposable Medical Labware and Instruments, Collection Swabs, Cervical Brushes, Cotton Swabs


TÜVRheinland®

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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: service
@de.tuv.com

Date December 03, 2021

Application for: QMS

Certificate No. : SX 2029176-1

Requirement : EN ISO 13485:2016

Dear Madame or Sir

Enclosed please find the new certificate No. SX 2029176-1 replacing the previous certificate.

With effective date of the new certificate, the previous certificate becomes invalid.

Best regards,


Fuxiu Sheng
Certification body

TÜV Rheinland
LGA Products GmbH

Am Grauen Stein
51105 Köln
Germany

Headquarter

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90431 Nuremberg

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Board of Management

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Nuremberg HRB 26013
VAT No.: DE 811835490

Chairman of the
Supervisory Board

Dipl.-Ing. Ralf Scheller

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CITOTEST Labware Manufacturing Co., Ltd.
No.339 Beihai West Road,
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226100 Jiangsu
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Contact

Tel. +49 911 655-5225
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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

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Germany

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Chairman of the
Supervisory Board

Dipl.-Ing. Ralf Scheller



TÜVRheinland®

LGAD

Precisely Right.

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