

Écouvillons secs stériles en tube

tige sécable en polystyrène / tête en visqueuse

certification

DM 93/42/CE

en cours

- **écouvillon** sécable stérile par rayons gamma
tige sécable en polystyrène sécable Ø 2,2 x 150 mm,
tête ronde en visqueuse Ø 5 mm, compacte, résistante au
déchetage, sans jeu lors de l'échantillonnage
- tube avec large zone de marquage

écouvillon sécable
stérile par rayons gamma



tige	extrémité	dim. tête	dim. tige	réf. LMR	réf. fabricant	Prix HT
polystyrène cassable	visqueuse	Ø 5 mm	Ø 2,2 x 150 mm	LMR190016	2120-0016	les 1000

EC Certificate
Directive 93/42/EEC Annex V
Production Quality Assurance
Medical Devices

Registration No.: DD 60125683 0001

Report No.: 15053823 008

Manufacturer: CITOTEST LABWARE
MANUFACTURING CO., LTD
No. 48, Xinxiu Road
Haimen City, Jiangsu 226100
China

Products: Medical Devices
(see attachment for products included)
Replaces Approval, Registration No.: DD 60100201 0001

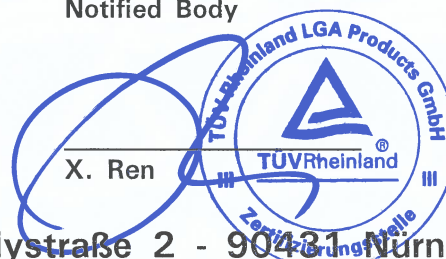
Expiry Date: 2022-10-23

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.

Effective Date: 2017-12-15

Date: 2017-12-15

Notified Body



TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg

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

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Doc. 1/1, Rev. 0

**Attachment to
Certificate**

Registration No.: DD 60125683 0001
Report No.: 15053823 008

Manufacturer: CITOTEST LABWARE
MANUFACTURING CO., LTD
No. 48, Xinxu Road
Haimen City, Jiangsu 226100
China

Products:

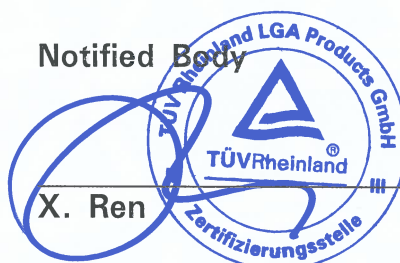
- Collection Swabs
- Blood Lancets
- Scalpel Blades
- Insulin Pen Needles
- Cervical Brushes
- Cervical Scrapers

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

Date: 2017-12-14

Notified Body



CITOTEST LABWARE MANUFACTURING CO., LTD

ISO 9001:2015

Issue 1.

Detailed scope

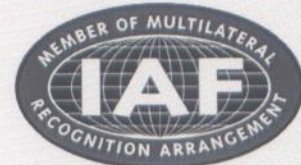
Manufacture disposable labware and instruments
(including microscope slides, microscope cover slides, tissue processing and embedding, plastic loops, petri dishes, tubes, specimen containers, multiwell plates, storage and transport)
Manufacture disposable labware and instruments
(including pasteur pipettes, swabs)

Further clarifications regarding the scope of this certificate and the applicability of ISO 9001:2015 requirements may be obtained by consulting the organisation

Additional facilities

CITOTEST LABWARE MANUFACTURING CO., LTD

No. 48 Xinxiu Road, Haimen City, Jiangsu Province, P.R. China



0005

Certificate CN18/21154.00

The management system of

CITOTEST LABWARE MANUFACTURING CO., LTD

No. 339 Beihai West Road, Haimen street,
Haimen City, Jiangsu Province, P.R. China
Unified Social Credit Code 9132068474065179XL

has been assessed and certified as meeting the requirements of

ISO 9001:2015

For the following activities

The scope of registration appears on page 2 of this certificate.

Further clarifications regarding the scope of this certificate and the applicability of
ISO 9001:2015 requirements may be obtained by consulting the organisation

This certificate is valid from 26 September 2018 until 25 September 2021
and remains valid subject to satisfactory surveillance audits.
Recertification audit due a minimum of 60 days before the expiration date
Issue 1. Certified since 26 September 2018

Multiple certificates have been issued for this scope
The main certificate is numbered CN18/21154.00

This is a multi-site certification.
Additional site details are listed on subsequent pages

Authorised by



SGS United Kingdom Ltd
Rossmore Business Park Ellesmere Port Cheshire CH65 3EN UK
t +44 (0)151 350-6666 f +44 (0)151 350-6600 www.sgs.com
The certification information can be verified on the web site of Certification and Accreditation
Administration of the People's Republic of China www.cnca.gov.cn



0005

HC SGS 9001-15 01 0118 M3

Page 1 of 2



Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

**CITOTEST LABWARE
MANUFACTURING CO., LTD**
No. 48, Xinxu Road
Haimen City, Jiangsu 226100
China

has established and applies a quality management system for medical devices
for the following scope:

Manufacture and Distribution of Medical Devices

(see attachment for products and additional site included)

Proof has been furnished that the requirements specified in

EN ISO 13485:2016

are fulfilled. The quality management system is subject to yearly surveillance.

Effective Date: 2017-11-09
Certificate Registration No.: SX 60124431 0001
An audit was performed. Report No.: 15053823 008
This Certificate is valid until: 2020-10-23

Certification Body



Date 2017-11-09



TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
Tel.: +49 221 806-1371 Fax: +49 221 806-3935 e-mail cert-validity@de.tuv.com <http://www.tuv.com/safety>

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

**Attachment to
Certificate**

Registration No.: SX 60124431 0001
Report No.: 15053823 008

Organization: CITOTEST LABWARE
MANUFACTURING CO., LTD
No. 48, Xinxiu Road
Haimen City, Jiangsu 226100
China

Scope:

Products:

- Disposable Medical Labware and Instruments
- Blood Lancets
- Wooden Tongue Depressors
- Cervical Scrapers
- Vaginal Speculums
- Scalpel Blades
- Insulin Pen Needles

Site included:

No.339, Beihai Road, Haimen City,
Jiangsu 226100, P.R. China

Manufacture of the a.m. products

Certification Body



Date: 2017-11-09



EC DECLARATION OF CONFORMITY

Document number / version : ST014-03

Name and address of the manufacturer:

CITOTEST LABWARE MANUFACTURING CO., LTD
ADDRESS:NO.48 XinXiu Road Haimen City JiangSu
Province 226100, PR China

We declare under our sole responsibility that

the medical device:

Cotton Swabs
Type: Attached Chart I

of class:

I *

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.

Conformity assessment procedure: /

Directive 93/42/EEC Annex V,

Registration No.:

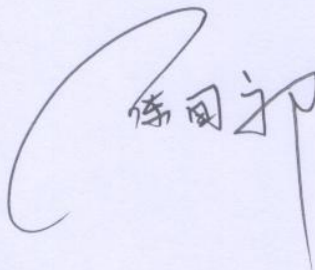
DD60125683 0001

Notified Body: /

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

HAIMEN Nov.12,2018
Place, date

CHENGUOQI (QUALITY MANAGER)
Name and function



Attached Chart I

2122-0004	2122-0011	2122-0018	2122-0022
2120-0010	2120-0012	2120-0022	2122-0231
2122-0232	2120-0021	2120-0017	2120-0023
2120-0018	2120-0019	2120-0005	2120-0006
2120-0007	2120-0008	2120-0009	2120-0011
2122-0013	2122-0202	2122-0021	2122-0008
2122-0017	2122-0012	2122-0002	2122-0201
2120-0001	2120-0002	2120-0003	2120-0004
2120-0013	2120-0014	2120-0015	2120-0016

