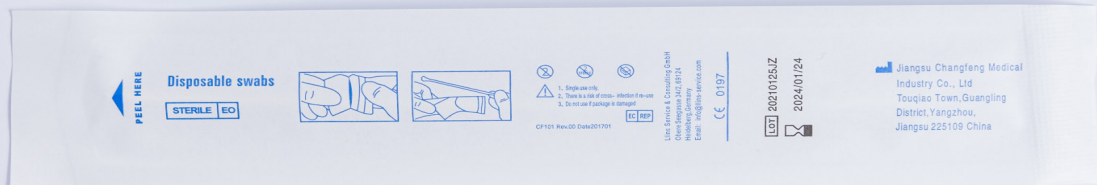


MedRhein SP01

Sterile Tupfer CE0197





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

Registration No.: DD 60133279 0001

Report No.: 15096049 004

Manufacturer: Jiangsu Changfeng Medical
Industry Co., Ltd.
Touqiao Town, Guangling District
Yangzhou
225109 Jiangsu
P.R. China

Products: Aspects of manufacture concerned with securing and
maintaining sterile conditions:

- Disposable Swabs

Replaces Approval, Registration No.: HD 60115109 0001

Expiry Date: 2023-12-03

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: 2020-03-11

Date: 2020-03-11

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.

Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

**Jiangsu Changfeng Medical
Industry Co., Ltd.**
Touqiao Town, Guangling District
Yangzhou
225109 Jiangsu
P.R. China

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

Manufacture and Distribution of Disposable Swabs

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: 2020-03-11
Certificate Registration No.: SX 60133280 0001
An audit was performed. Report No.: 15096049 004
This Certificate is valid until: 2021-12-03

Certification Body



Date 2020-03-11



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

**Business Stream Products
Certification Department**



TÜVRheinland®

LGA

Precisely Right.

TÜV Rheinland LGA Products GmbH · 90431 Nürnberg

Jiangsu Changfeng Medical
Industry Co., Ltd.
Touqiao Town, Guangling District
Yangzhou
225109 JIANGSU
P.R. CHINA

Contact

Tel. +49 911 655-5225
Mail service@de.tuv.com

Date May 29, 2020

Application for : QMS Produktion, Anhang V MDD
Certificate No. : DD 60133279 Sheet 0001
Device : Only for QM-System audit
Test requirement : Richtlinie 93/42/EWG

Dear Madame or Sir,

Enclosed please find the new certificate No. DD 60133279 0001 replacing
the previous certificate.

With effective date of the new certificate, the previous certificate
(number see new certificate) becomes invalid.

Kind regards

Certification body

Fuxiu Sheng

Test sample: no, documentation available

TÜV Rheinland
LGA Products GmbH

Tillystraße 2
90431 Nürnberg

Tel. +49 911 655-5225
Fax +49 911 655-5226
Mail service@de.tuv.com
Web www.tuv.com/safety

Board of Management

Dipl.-Ing.
Jörg Mähler, Spokesman

Dipl.-Kfm.
Dr. Jörg Schlösser

Chairman of the
Supervisory Board

Dipl.-Ing.
Ralf Scheller

Nuremberg HRB 26013
VAT No.: DE 811835490

**Business Stream Products
Certification Department**



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TÜV Rheinland LGA Products GmbH · 90431 Nürnberg

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Touqiao Town, Guangling District
Yangzhou
225109 JIANGSU
P.R. CHINA

Contact

Tel. +49 911 655-5225
Mail service@de.tuv.com

Date March 12, 2020

Application for : QMS
Certificate No. : SX 60133280 Sheet 0001
Device : Only for QM-System audit
Test requirement : EN ISO 13485:2016

Dear Madame or Sir,

Enclosed please find the
new certificate No. SX 60133280 0001
replacing the previous certificate.

Kind regards

Certification body

Fuxiu Sheng

Test sample: no, documentation available

TÜV Rheinland
LGA Products GmbH

Tillystraße 2
90431 Nürnberg

Tel. +49 911 655-5225
Fax +49 911 655-5226
Mail service@de.tuv.com
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