Business Stream Products
Certification Department

TÜVRheinland®
LGA
Precisely Right.

TÜV Rheinland LGA Products GmbH · 90431 Nürnberg

Zhejiang Runlab Technology
Co., Ltd.
No. 6, Minghui Rd., Xinqian Street
Huangyan, Taizhou
318020 ZHEJIANG
CHINA

Contact

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

Date January 02, 2019

Application for : QMS Produktion, Anhang V MDD
Certificate No. : DD 60131250 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 60131250 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

Herbert Zhong

Test sample: no, documentation available

TÜV Rheinland
LGA Products GmbH

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EC Certificate

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

Registration No.: DD 60131250 0001

Report No.: 15096002 004

Manufacturer:
Zhejiang Runlab Technology
Co., Ltd.
No. 6, Minghui Rd., Xinqian Street
Huangyan, Taizhou
318020 Zhejiang
China

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

Replaces Approval, Registration No.: DD 60123388 0001

Expiry Date: 2023-07-11

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: 2019-01-02

Date: 2019-01-02

Notified Body

Herbert Zhong

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.