Business Stream Products
Certification Department

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LGA
Precisely Right.

TÜV Rheinland LGA Products GmbH • 51105 Köln

Suzhou Laishi Transfusion Equipment Co., Ltd.
Changsheng Rd., Tongli Town, Wujiang District
Suzhou City,
215217 Jiangsu Province
P.R. China

Contact

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

Date September 28, 2023

Digitally signed by Moraru Grigore
Date: 2023.11.15 10:59:24 EET
Reason: MoldSign Signature
Location: Moldova

Application for: QMS

Certificate No.	: HD 60139767 0001
Requirement	: Richtlinie 93/42/EWG
Confirmation letter ID	: DOC_2023-09-27_HD 60139767 0001
Report no.	: 244528331-200

Dear Madame or Sir,

Update of information to Certificate no. HD 60139767 0001, issued on 03.04.2020

The change notification received on 27.04.2023 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

Additional location address

New location designation: Shanghai Transfusion Technology Co., Ltd.
No.500 Youdong Road, Minhang District, 201100
Shanghai, P.R. China

A surveillance audit of your quality management system was performed.

The audit team confirmed that your quality management system is applied effectively with respect to the above-mentioned requirement.

This letter confirms that the above-mentioned certificate will remain valid.

Best regards,

Herbert Zhong
Certification body

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LGA Products GmbH

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TÜVRheinland®

EC Certificate

Directive 93/42/EEC Annex II, excluding Section 4
Full Quality Assurance System
Medical Devices

Registration No.: HD 60139767 0001

Report No.: 15071307 008

Manufacturer:
Suzhou Laishi Transfusion
Equipment Co., Ltd.
Changsheng Rd., Tongli Town
215217 Wujiang City, Jiangsu Province
China

Products:
Disposable Plastic Blood Bags

Replaces Approval, Registration No.: HD 60095681 0001

Expiry Date: 2024-05-27

The Notified Body hereby declares that the requirements of Annex II, excluding section 4 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 II, section 5 of the aforementioned directive. For placing on the market of class III devices covered by this certificate an EC design-examination certificate according to Annex II, section 4 is required.

Effective Date: 2019-08-01

Date: 2019-08-01

Notified Body

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle

Fuxiu Sheng

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.