EC Certificate

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

Registration No.: HD 60145460 0001

Report No.: 17054641 002

Manufacturer:

Shenzhen MedRena Biotech Co., Ltd.
4th Floor, Office Building, Silcon Industrial Park
No.3 Kaitian Road, Pinghu Street
Longgang District
518111 Shenzhen
P.R. China

Products:

- Syringe Pumps
- Infusion Pumps

Digitally signed by Jighili Tatiana
Date: 2023.08.28 12:20:26 EEST
Reason: MoldSign Signature
Location: Moldova

Expiry Date: 2024-05-26

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.

Notified Body

Effective Date: 2020-03-12

Date: 2020-03-12

Dipl.-Ing. I. Munkler

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.

Business Stream Products
Certification Department

TÜVRheinland®
LGA
Precisely Right.

TÜV Rheinland LGA Products GmbH • 51105 Köln

Shenzhen MedRena Biotech Co., Ltd.
702, Block A, Youlitong Technology Industrial Park,
No. 56 Qingsong Road, Laokeng Community, Longtian Street,
Pingshan District, 518122, Shenzhen,
P.R. China

Contact

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

Date October 28, 2022

Application for: QMS
Certificate No. : HD 60145460 0001
Requirement : Richtlinie 93/42/EWG
Confirmation letter ID : 2020-03-12_ HD 60145460 0001
Report no. : 10920596-100

Dear Madame or Sir,

Update of information to Certificate no. HD 60145460 0001, issued on 28.10.2022

The change notification received on 25.03.2022 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

Revised Manufacturer address

Old Manufacturer address:	4th Floor, Office Building, Silcon Industrial Park, No.3 Kaitian Road, Pinghu Street, Longgang District, 518111, Shenzhen, P.R. China
New Manufacturer address:	702, Block A, Youlitong Technology Industrial Park, No. 56 Qingsong Road, Laokeng Community, Longtian Street, Pingshan District, 518122 Shenzhen, P.R. China

Best regards,

Dipl.-Ing. W. Hsu

Certification body

TÜV Rheinland
LGA Products GmbH

Am Grauen Stein
51105 Köln
Germany

Headquarter

Tillystraße 2
90431 Nuremberg

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702, Block A, Youlitong Technology
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Laokeng Community, Longtian Street, Pingshan District
518122 Shenzhen
P.R. China

Contact

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

Date September 26, 2022

Application for: QMS
Certificate No.: SX 2099948-1
Requirement : EN ISO 13485:2016

Dear Madame or Sir

Enclosed please find the new certificate No. SX 2099948-1 replacing the previous certificate.

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

Best regards,

Dipl.-Ing. W. Hsu
Certification body

TÜV Rheinland
LGA Products GmbH

Am Grauen Stein
51105 Köln
Germany

Headquarter

Tillystraße 2
90431 Nuremberg

Phone. +49 911 655 5225
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service@de.tuv.com
www.tuv.com/safety

Certificate

TÜVRheinland®

Quality Management System
EN ISO 13485:2016

Registration No.: SX 2099948-1

Organization: Shenzhen MedRena Biotech Co., Ltd.
702, Block A, Youlitong Technology
Industrial Park, No. 56 Qingsong Road,
Laokeng Community, Longtian Street, Pingshan District
518122 Shenzhen
P.R. China

Scope: Design and Development, Manufacture and Distribution of Syringe Pumps and Infusion Pumps

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.: 10920596-100
Effective date: 2022-10-02
Expiry date: 2025-10-01
Issue date: 2022-09-26

TÜV Rheinland LGA Products GmbH TÜVRheinland® Zertifizierungsstelle

Dipl.-Ing. W. Hsu
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

DAkkS Deutsche Akkreditierungsstelle D-ZM-14169-01-02