

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

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 the product of the directive section.

Effective Date: 2020-03-12

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Dipl.-Ing. I. Munkler

ÜVRheinland

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.