EC Certificate

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

Registration No.: HD 60144003 0001

Report No.: 17055844 008

Manufacturer:
Shenzhen Enmind Technology
Co., Ltd.
Room 201, Block A
No. 1, Qianhai Road 1
Qianhaishen Port Cooperative District
Shenzhen
518000 Guangdong
China

Products: Infusion Pumps, Syringe Pumps

(see attachment for site included)

Replaces Approval, Registration No.: DD 60109366 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: 2019-12-02

Date: 2019-12-02

Notified Body
TÜV Rheinland LGA Products GmbH
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.

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TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: HD 60144003 0001
Report No.: 17055844 008

Manufacturer:
Shenzhen Enmind Technology Co., Ltd.
Room 201, Block A
No. 1, Qianhai Road 1
Qianhaishen Port Cooperative District
Shenzhen
518000 Guangdong
China

Site included:

5th Floor, Block A, Defengsheng Building,
No.41 Dabao Road, Bao'an District 23,
Shenzhen, 518101, P.R.China

Notified Body

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle

Fuxiu Sheng

Date: 2019-12-02