

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

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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Doc. 1/1, Rev. 0

Attachment to Certificate

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Qianhaishen Port Cooperative District

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518000 Guangdong

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Site included:

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

Date: 2019-12-02

10050 a 04.00 to 10V, TuTV and TUV are registered usdemarks. Utilisa ion and application requires trian spensys

