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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 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
TÜV Rheinland®
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.

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Doc. 1/1, Rev. 0

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

Certificate

TÜVRheinland®

Quality Management System
EN ISO 13485:2016

Registration No.: SX 2042744-1

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

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

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.: 10918665-100
Effective date: 2021-09-02
Expiry date: 2024-09-01
Issue date: 2021-09-02

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

Certificate

TÜVRheinland®

Quality Management System
EN ISO 13485:2016

Registration No.: SX 2042744-1

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

The scope of certification also covers the following:

No.	Facility	Scope
/01	c/o Shenzhen Enmind Technology Co., Ltd. Room 201, Block A, No.1, Qianhai Road 1, Qianhaishen Port Cooperative District Shenzhen 518000 Guangdong P.R. China	License holder
/02	c/o Shenzhen Enmind Technology Co., Ltd. 5th Floor, Block A, Defengsheng Building, No.41 Dabao Road, Bao'an District 23, Shenzhen, 518101 Guangdong P.R. China	Design and Development, Manufacture and Distribution of Infusion Pumps, Syringe Pumps and Infusion Workstations

Report No.: 10918665-100
Effective date: 2021-09-02
Expiry date: 2024-09-01
Issue date: 2021-09-02

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle

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

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