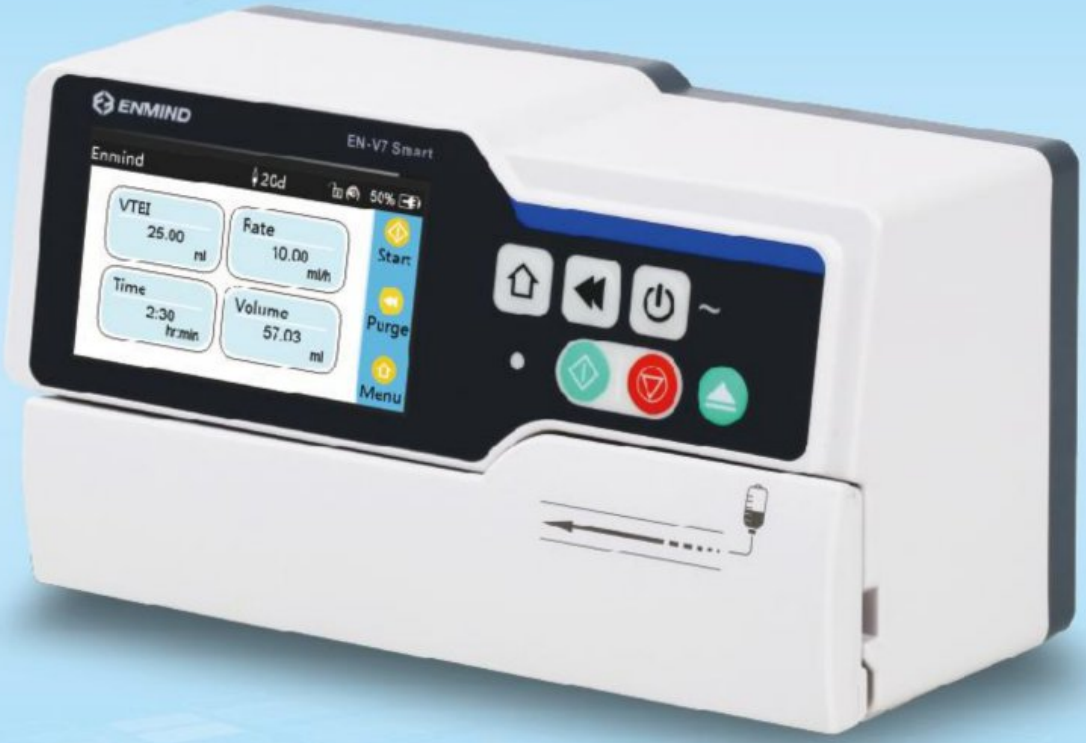
ENMIND



EN-V7 Smart Infusion Pump

- 4.3 inch color touch screen
- Up & down pressure sensor
- Electric door & electric anti-free flow clip
- Parameter setting and editing directly on touch screen
- 7 Infusion modes + Micro mode + Relay mode
- Alarm volume and brightness adjustable
- History record more than 5000 logs
- IrDA, WIFI, nurse call, RS232, data export
- 9 hours battery back-up time
- IP24 waterproof
- Support the blood transfusion

ISO ISO 13485 CE 0197 CFDA

EN-V7 Smart Infusion Pump

Basic Parameters	
Screen	4.3 inch LCD color touch screen
Infusion Mode	ml/h (include Rate mode, Time mode), Body weight, Drip, Loading-dose, Ramp up/down, Sequence, Drug Library mode
Accuracy	±5%
Flow Rate Range	0.01-2000ml/h (increment 0.01ml/h)
VTBI	0-9999ml
KVO	0.01-5ml/h adjustable
Bolus Rate	0.1-2000ml/h(automatic & manual bolus available)
Occlusion Level	12 levels selectable
Interface	MINI USB
Wireless	Wifi (optional)
Alarm Type	VTBI Infused, Pressure high, Check upstream, Battery empty, KVO finished, Door Open, Air bubble, VTBI near end, Battery near empty, Reminder alarm, No power supply, Drop sensor connection, System error, etc.

Special Features	
Titration	Change flow rate without stopping infusion
Last Therapy	Last therapies can be stored and used for rapid infusion
Drug Library	No less than 2000 drugs
Anti-Bolus	Automatic drop line pressure to reduce bolus impact after occlusion
Purge	Remove the air bubble
Screen Lock	Avoid misoperation
Standby Mode	Standby time 00-99h59m adjustable
Relay Mode	Different pumps work in sequence on infusion workstation (optional)
Micro Mode	Limit the max infusion rate to double ensure patient safety
DPS	Real-time pressure display in graphically and numerically
Bubble Detector	Adjustable
Brightness	Adjustable
Alarm Volume	Adjustable
History Record	More than 5000 entries

Power Source	
AC Power	110V-240V, 50/60Hz
External DC Power	12V
Battery	Lithium Polymer battery 11.1V 2600mAh
	More than 9 hours operating time @ 25ml/h
	Less than 5 hours for fully charged

Others	
Classification	Class I, CF
Waterproof	IP24
Dimension	235(L)*95(W)*120(H) mm
Weight	Approx. 1.6kg

ENMIND

Shenzhen ENMIND Technology Co., Ltd.
5th Floor, Block A, Defengsheng Building, No. 41 Dabao Road,
Bao'an District 23, Shenzhen 518101, P.R. China
E-mail: sales@enmind-tech.com
Web: www.enmind-tech.com
Tel: 0755-2331 6007

EC Declaration of Conformity

Manufacturer:

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

whose single Authorized Representative:

Shanghai International Holding Corp. GmbH (Europe)
Eiffestrasse 80, 20537 Hamburg，Germany

We, the manufacturer, herewith declare that the products

Infusion Pumps(EN-V7,EN-V7 Smart)
UMDNS-Code: **13215**
Syringe Pumps (EN-S7,EN-S7 Smart)
UMDNS-Code: **13217**
Infusion Work Station(EN-D7,EN-D7 Smart)
UMDNS-Code: **13217**
(Including system compenents and accessories, Annex I)

meet the provisions of Directive 93/42/EEC which apply to them.

The medical device has been assigned to class IIb according to Annex IX of the Directive 93/42/EEC. It bears the mark

CE 0197

The product concerned has been manufactured under a quality management system according to Annex II of Directive 93/42/EEC.

Compliance of the designated product with the Directive 93/42/EEC has been assured via assessment of the quality management system by the Notified Body

TÜV Rheinland LGA Products GmbH
Tillystraße 2, 90431, Nürnberg, Germany
Certificate No.: HD 60144003 0001
Issue date: 2019-12-02
Expiry date: 2024-05-27

following the procedure relating to the EC Declaration of Conformity set out in Annex II of Directive 93/42/EEC.

This Declaration of Conformity covers all medical devices as specified in the product list belonging to this declaration and is only valid in connection with a batch specific Certificate of Compliance for all products concerned bearing the CE mark.

The above mentioned declaration of conformity is exclusively under the responsibility of

Company: Shenzhen Enmind Technology Co., Ltd.
Address: 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

Shenzhen 2019.12.02
Place, date

Lingxiang, Legal person.
Legally binding signature, Function

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.

TÜVRheinland®

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

TÜVRheinland®

Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

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

has established and applies a quality management system for medical devices for the following scope:

Design and Development, Manufacture and Distribution of Infusion Pumps, Syringe Pumps and Infusion Workstations (see attachment for additional site included)

Proof has been furnished that the requirements specified in

EN ISO 13485:2016

are fulfilled. The quality management system is subject to yearly surveillance.

Effective Date:	2019-05-28
Certificate Registration No.:	SX 60131044 0001
An audit was performed. Report No.:	17055844 003
This Certificate is valid until:	2021-09-25

Certification Body

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

TÜV Rheinland LGA Products GmbH
TÜVRheinland®
Zertifizierungsstelle

Date 2019-05-28

Dipl.-Ing. I. Munkler

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
Tel.: +49 221 806-1371 Fax: +49 221 806-3935 e-mail:cert-validity@de.tuv.com http://www.tuv.com/safety

TÜVRheinland®

Doc. 1/1, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: SX 60131044 0001
Report No.: 17055844 003

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

Scope:

Site included:

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

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

Certification Body

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

TÜVRheinland LGA Products GmbH Zertifizierungsstelle

Date: 2019-05-28

Dipl.-Ing. I. Munkler