EC Declaration of Conformity

Manufacturer:

whose single Authorized Representative:

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

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,EN-V5,EN-Z50,EN-V3,EN-Z30,EN-V9,EN-V9 Smart)

GMDN-Code: 13215

BASIC-UDI-DI: 697100143001001BR

Syringe Pumps (EN-S7,EN-S7 Smart ,EN-S3,EN-S5D,EN-S9,EN-S9Smart)

GMDN-Code: 13217

BASIC-UDI-DI: 697100143002001BY

Infusion Work Station(En-D7,EN-D7 Smart, En-D9,EN-D9 Smart,)

GMDN- Code: 13217

BASIC-UDI-DI: 697100143004001CE

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

C €0197

The product concerned has been manufactured under a quality management system according to Annex Π 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 2021.05.20

Place, date

Legally binding signature Function