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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,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

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 2021.05.20
Place, date

Legally binding signature, Function