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-V5/EN-Z50/EN-V3/EN-Z30)
UMDNS-Code: **13215**
Syringe Pumps (EN-S3)
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.
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Shenzhen 2020.06.17
Place, date

Legally binding signature, Function