EC Declaration of Conformity

Manufacturer:

Shenzhen Dongdixin Technology Co., Ltd.

Floor 1-2, No.3 Building, Fanshen Xusheng

Industrial Estate Xilixiaobaimang 518108

Nanshan District, Shenzhen P. R. China

Tel: (86) 755 2765 2471

Fax: (86) 755 2765 2674

Authorized Representative:

Shanghai international holding Corp. GmbH (Europe)

Eiffestraβe 80, 20537 Hamburg Germany

Tel: 0049-40-2513175

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DIMDI No.: DE/0000040627

We, the manufacturer, herewith declare that the products

Nerve and Muscle Stimulator (MIO-CARE FITNESS)

Model: LT3016A

*(*including system components and accessories*)*

UMDNS-Code: **13762**

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

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

CE 0197

The product concerned has been designed and manufactured under a quality management system according to Annex II, excluding Section 4 of Directive 93/42/EEC.

Compliance of the quality management system with the Directive 93/42/EEC have been assessed and certified by the Notified Body

TÜV Rheinland LGA Products GmbH
Tillystraße 2 - 90431, Nürnberg, Germany
Certificate No.: HD 60147882 0001
Issue date: 03 August, 2020
Expiry date: 26 May, 2024

following the procedure relating to the EC Declaration of Conformity set out in Annex II, excluding Section 4 of Directive 93/42/EEC.

This Declaration of conformity is valid in connection with the release document for the respective batch of produced devices.

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

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Address: Floor 1-2, No.3 Building, Fanshen Xusheng Industrial Estate
Xilixiaobaimang 518108 Nanshan District, Shenzhen P. R. China

2021-2-25, Shenzhen
Place, date

Siping Yuan, R.A. Supervisor
Legally binding signature, Function