

File No.: SDT-DEL-202405001

EC Declaration of Conformity

Manufacturer:

Authorized Representative:

Shenzhen Dongdixin Technology Co., Ltd.

Shanghai international holding Corp. GmbH (Europe)

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

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DIMDI No.: DE/0000040627

We, the manufacturer, herewith declare that the products

Nerve and Muscle Stimulator (MIO-CARE TENS)

Model: LT3016

(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

C € 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

Company: Shenzhen Dongdixin Technology Co., Ltd.

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