

File No.: SDT-DEL-202405008

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

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Authorized Representative:

Shanghai international holding Corp. GmbH (Europe)

Eiffestraße 80, 20537 Hamburg Germany

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DIMDI No.: DE/0000040627

We, the manufacturer, herewith declare that the products

Electromagnetic Stimulator Model: NEW MAG1000 (MAG1000)

(including system components and accessories)

UMDNS-Code: 12415

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

2021-1-5, Shenzhen

Place, date

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

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