

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 Fax: 0049-40-255726 DIMDI No.: DE/0000040627

We, the manufacturer, herewith declare that the products **Combo Stimulator LT7102** (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



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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Jianping Kang, Vice president Legally binding signature, Function

2021-3-19, Shenzhen Place, date