

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
Tel: 0049-40-2513175
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DIMDI No.: DE/0000040627

We, the manufacturer, herewith declare that the products

Ultrasound Physical Therapy Device
Model: UT1032 (Mio-Sonic)
(including system components and accessories)
UMDNS-Code: 11248

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

Company: Shenzhen Dongdixin Technology Co., Ltd.

Address: Floor 1-2, No.3 Building, Fanshen Xusheng Industrial Estate
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2021-1-5, Shenzhen
Place, date


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