

File No.: SDT-DEL-202101002

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)

Eiffestraße 80, 20537 Hamburg Germany

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DIMDI No.: DE/000040627

We, the manufacturer, herewith declare that the products

Portable ultrasound therapy equipment, UT1033

(Including system components and accessories)

UMDN-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

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 designated product 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 Aug. 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

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Address: Floor 1-2, No.3 Building, Fanshen Xusheng Industrial Estate

Xilixiaobaimang 518108 Nanshan District, Shenzhen P. R. China

Shenzhen, 2021-01-05 Place, date

Jianping Kang, Vice president Legally binding signature, Function