EC Declaration of Conformity

Manufacturer:

EasyMed Instruments Co., Ltd.

3/F, 5/F-6/F, Blk A, Gupo Gongmao Building,
Fengxin Road, Fengxiang Industrial District,
Daliang, 528300 Shunde, Foshan, Guangdong,
China

whose single Authorized Representative:

Mdi Europa GmbH

Langenhagener Str. 71, 30855 Langenhagen,
Germany

We, the manufacturer, herewith declare that the products

TENS UD

meet the provisions of Directive 93/42/EEC and Directive 2011/65/EU (RoHS 2) 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

CE 0197

The product concerned has been designed and manufactured under a quality management system according to Annex V of Directive 93/42/EEC.

Compliance of the designated product with the Directive 93/42/EEC has been assessed and certified by the Notified Body

TÜV Rheinland LGA Products GmbH
Tillystraße 2, 90431, Nürnberg, Germany
Registration No.: DD 60129671 0001
Effective date: 2018-08-16
Expiry date: 2023-04-09

following the procedure relating to the EC Declaration of Conformity set out in Annex V 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

EasyMed Instruments Co., Ltd.

3/F, 5/F-6/F, Blk A, Gupo Gongmao Building,
Fengxin Road, Fengxiang Industrial District,
Daliang, 528300 Shunde, Foshan, Guangdong, China

CHINA, 25 March, 2021

Place, date

Management Representative

Legally binding signature, Function