

EC Certificate
Directive 93/42/EEC Annex V
Production Quality Assurance
Medical Devices

Registration No.: DD 60129671 0001

Report No.: 17030157 007

Manufacturer: EasyMed Instruments Co., Ltd.
3/F, 5/F- 6/F, Block A, Gupo Gongmao
Building, Fengxin Road, Fengxiang
Industrial District, Daliang,
528300 Shunde, Foshan, Guangdong
China

Products:

- Neuromuscular Stimulators
- Transcutaneous Electrical Nerve Stimulators
- TENS/EMS/ Micro-current/ Interferential Stimulators
- Peripheral Nerve Stimulators
- Transcutaneous Vagus Nerve Stimulators (tVNS)

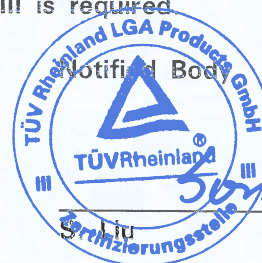
Replaces Approval, Registration No.: DD 60114968 0001

Expiry Date: 2023-04-09

The Notified Body hereby declares that the requirements of Annex V of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex V, section 4 of the aforementioned directive. For placing on the market of class IIb and class III devices covered by this certificate an EC type-examination certificate according to Annex III is required.

Effective Date: 2018-08-16

Date: 2018-08-16



TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC
concerning medical devices with the identification number 0197.

Date: 3rd July 2023

Statement for Extension of MDD certificate

EasyMed Instruments Co., Ltd. herewith declares that the conditions granted by Regulation (EU) 2023/607 are fulfilled for the extension of the validity of MDD certificates.

Compliance of the designated product with the Regulation (EU) 2017/745 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: 218-08-16

Expiry date: 2023-04-09

Extension date: 2028-12-30

In particular, I declare that:

- 1) Before the date of expiry of the certificates, EasyMed Instruments Co., Ltd and its Notified Body TÜV Rheinland LGA Products GmbH have signed a written agreement in accordance with Section 4.3, second subparagraph, of Annex VII to MDR for the conformity assessment.
- 2) The devices covered by the MDD certificate (Registration No.: DD 60129671 0001) continue to comply with the MDD.
- 3) During the extension period, no significant change will be applied to the design and intended purpose of the medical devices covered by the extension.
- 4) The devices do not present an unacceptable risk to the health or safety of patients, users or other persons, or to other aspects of the protection of public health.
- 5) EasyMed Quality Management System complies with Article 10(9) of MDR. For such Quality Management System, EasyMed holds an ISO 13485:2016 certificate SX 2101683-1 issued by TÜV Rheinland LGA Products GmbH Certification, valid until 2024-4-09.
- 6) The applications for certification under MDR and the Technical Documentation have been acknowledged by TÜV Rheinland LGA Products GmbH.

A complete list of devices covered by the extension is listed below:

- Neuromuscular Stimulators
- Transcutaneous Electrical Nerve Stimulators
- TENS/EMS/Micro-current/Interferential Stimulators
- Peripheral Nerve Stimulators
- Transcutaneous Vagus Nerve Stimulators

Signature:



Winnie Lee

General Manager

EasyMed Instruments Co., Ltd.