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 deciares 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

Notified Body
TÜV Rheinland LGA Products GmbH
TÜVRheinland
Prüfzierungsstelle
Liu

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.

Add: 3/F-6/F, No. 4, Fengxin Road, Fengxiang Industrial District, Daliang, Shunde, Foshan, Guangdong, China.
Tel: 86-757-28091300 Fax: 86-757-27727868 Post Code: 528300
Web: http://www.EasyMed.com.cn E-mail: info@EasyMed.com.cn

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.

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