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
Prüfzierungsstelle
S. 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.

TÜVRheinland®

2023-03-31

To Whom It May Concern,

This is to confirm that 2nd Surveillance Audit for EN ISO 13485, Surveillance Audit for MDD, Facility Extension Audit was carried out on behalf of TÜV Rheinland LGA Product GmbH Notified Body (CE0197) as follows:

Applicant	:	EasyMed Instruments Co., Ltd.
Address	:	3/F-6/F, Block A, No.4, Fengxin Road, Fengxiang Industrial District, Daliang, Shunde, Foshan 528300 Guangdong, P.R. China
Standards	:	EN ISO 13485:2016 MDD 93/42/EEC Annex V
Scope	:	Manufacture and Distribution of Neuromuscular Stimulators, Transcutaneous Electrical Nerve Stimulators, TENS/EMS/Micro-current/Interferential Stimulators, Peripheral Nerve Stimulators, Transcutaneous Vagus Nerve Stimulators (tVNS)
Date	:	2023-02-22~23
Report No.	:	10922264-100

No nonconformities were established what would affect the overall effectiveness of the QM-system. Therefore the auditors will recommend that TÜV Rheinland LGA Product GmbH Notified Body (0197) Certificate for a Quality Assurance System should be updated.

Yours sincerely,

Ms. Eileen YANG Eileen Yang

Lead auditor

TÜV RHEINLAND (SHENZHEN) Co., Ltd.