

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

Registration No.: DD 60131152 0001

Report No.: 15059181 007

Manufacturer: Jiangsu Neucognic
Medical Co., Ltd.
Room 308, 309, 11 Sihai Road,
Changshu Economic and
Technological Development Zone
215513 Changshu, Jiangsu
China

Products: External Functional Neuromuscular Stimulators
Replaces Approval, Registration No.: DD 60084675 0001

Expiry Date: 2023-06-25

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: 2018-12-21

Date: 2018-12-21



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.

EC Declaration of Conformity

Manufacturer:

Jiangsu Neucognic Medical Co., Ltd.
Address: Room 308, 309,11 Sihai Road, Changshu
Economic and Technological Development Zone,
215513 Changshu, Jiangsu, China

European Authorized Representative:

Prolinx GmbH
Address: Brehmstr.56,40239,Duesseldorf ,Ger
many

We, the manufacturer, herewith declare under our sole responsibility that the products
External Functional Neuromuscular Stimulators
Model No.NeuGait500, NeuGait501, NeuGait502, NeuGait505

meet the provisions of Directive 93/42/EEC which apply to them.

The medical device has been assigned to class **Ia** according to Annex IX of the Directive 93/42/EEC. It bears the mark

CE 0197

Conformity assessment procedure :Directive 93/42/EEC AnnexVII in connection with annexV
Compliance of the designated product with the Directive 93/42/EEC has been assured via
assessment of the quality management system by the Notified Body

TÜV Rheinland LGA Products GmbH
Tillystraße 2, 90431, Nürnberg, Germany

Certificate No.DD601311520001

Issue date:

Expiry date: 2023-6-25

Changshu
2022.3.18

Place, date

QA Manager

Yunyazhou, Function