



Australian Government
Department of Health
Therapeutic Goods Administration

Australian Register of Therapeutic Goods Certificate

Issued to

AIMedical International Pty Ltd

for approval to supply

AIMedical International Pty Ltd - Steadys Gait Trainer - Analyser, gait

ARTG Identifier	332543
ARTG Start date	26/03/2020
Product Category	Medical Device Included Class IIa
GMDN	35757
GMDN Term	Analyser, gait
Intended Purpose	<p>The gait trainer is intended for objective assessment of gait function and rehabilitation of patients with gait disorders associated with locomotion system, peripheral nervous system, central nervous system and somatic symptoms. The gait trainer ensures rehabilitation using biological feedback (BFB) method and allows monitoring of rehabilitation dynamics through the data obtained with IMU (Inertial Measurement Unit) sensors.</p> <p>The systems can be used in different health care facilities (including clinics, hospitals, health centres, ambulance centres, etc.), specialised medical facilities (including prevention centres, medical centres for emergency, military and medical expertise centres), research and educational medical and biological facilities.</p>

Manufacturer Details	Address	Certificate number(s)
Neurosoft LLC	5 Voronin Str , Ivanovo, 153032 Russian Federation	DV-2020-MC-04250-1

ARTG Standard Conditions

The above Medical Device Included Class IIa has been entered on the Register subject to the following conditions:

- The inclusion of the kind of device in the ARTG is subject to compliance with all conditions placed or imposed on the ARTG entry. Refer Part 4-5, Division 2 (Conditions) of the Therapeutic Goods Act 1989 and Part 5, Division 5.2 (Conditions) of the Therapeutic Goods (Medical Devices) Regulations 2002 for relevant information.
- Breaching conditions of the inclusion related to the device of the kind may lead to suspension or cancellation of the ARTG entry; may be a criminal offence; and civil penalties may apply.

Products Covered by This Entry

1. Steadys Gait Trainer - Analyser, gait

Product Specific Conditions

No specific conditions have been recorded against this entry.

