

## **Australian Government**

## **Department of Health**

## Therapeutic Goods Administration

### **Public Summary**

Summary for ARTG Entry: 343741 Neurotechnology - Tranceducer CognitiVR - Virtual-display rehabilitation system, non-supportive, clinical

ARTG entry for Medical Device Included Class 1

Sponsor Neurotechnology

Postal Address PO Box 424, Edgecliff, NSW, 2027

18/09/2020 ARTG Start Date

**Product Category** Medical Device Class 1

Status Active

Medical Devices Approval Area

### 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.

#### Manufacturers

Name Address

Neurotechnology 6/201 New South Head Road

Edgecliff, NSW, 2027

Australia

#### **Products**

# 1 . Tranceducer CognitiVR - Virtual-display rehabilitation system, non-supportive, clinical

**Product Type Effective Date** 18/09/2020 Medical device system

GMDN 60925 Virtual-display rehabilitation system, non-supportive, clinical

**Intended Purpose** An assembly of devices intended to be used in a clinical setting to provide non-gravity-compensating psychological rehabilitation

therapy for neuromuscular/musculoskeletal conditions affecting the back/trunk/limbs (e.g., impaired limb function) through patient interaction with a videogame-like display prompting repeated motion of a body part (e.g., arm, hand, leg) for functional improvement and pain reduction \ (e.g., reaching, grasping, balance); it may also provide performance feedback. It does not provide weight support and is based on motion-sensing devices [e.g., battery-powered patient-worn infrared (IR) glove, movement tracking camera, software] that communicate wirelessly to provide a virtual-display interface.

**Specific Conditions** 

No Specific Conditions included on Record

© Commonwealth of Australia. This work is copyright. You are not permitted to re-transmit, distribute or commercialise the material without obtaining prior written approval from the Commonwealth. Further details can be found at http://www.tga.gov.au/about/website-copyright.htm.