



Australian Government
Department of Health
 Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry: 295763 Emergo Asia Pacific Pty Ltd T/a Emergo Australia - Psychological assessment system application software

ARTG entry for Medical Device Included Class 1
Sponsor Emergo Asia Pacific Pty Ltd T/a Emergo Australia
Postal Address Level 20 Tower II Darling Park 201 Sussex Street, SYDNEY, NSW, 2000 Australia
ARTG Start Date 1/11/2017
Product category Medical Device Class 1
Status Active
Approval area Medical Devices

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
Qbtech AB	Kungsgatan 29 , Stockholm, 111 56 Sweden

Products

1. Psychological assessment system application software

Product Type	Single Device Product	Effective date	1/11/2017
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GMDN 58290 Psychological assessment system application software

Intended purpose The device provides professionals with objective measurements of hyperactivity, impulsivity, and inattention to aid in the clinical assessment of ADHD and in the evaluation of treatment interventions in patients with ADHD. Results should be interpreted by qualified professionals.

Specific Conditions

No Specific Conditions included on Record

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