Public Summary

Summary for ARTG Entry: 219452 Emergo Asia Pacific Pty Ltd T/a Emergo Australia - Patient data recorder, long-term, physical activity

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	22/01/2014
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
CamNtech Ltd	Upper Pendrill Court Ermine Street North Papworth Everard, Cambridge, CB23 3UY United Kingdom

Products

1. Patient data recorder, long-term, physical activity

Product Type	Medical device system	**Effective date**	22/01/2014

GMDN	36252 Patient data recorder, long-term, physical activity
Intended purpose	The system consists of a wrist-worn electronic patient diary and associated PC program which can record the user's answers to questions during daily living in a very flexible and easy to use way. The system also incorporates a tri-axial accelerometer to allow objective actigraphy data to be collected while the device is worn. Actigraphy data may be saved and loaded into the program for analysis of sleep, Circadian rhythm, and activity levels. The system can be used to monitor a wearer's condition and symptoms before treatment, or detect a change in the wearer's symptoms during or after intervention. It can also be used to remind the wearer to take treatment at regular or irregular intervals or to record events when marked by the wearer. The system is very flexible to different recording requirements for various areas of research.

Specific Conditions

No Specific Conditions included on Record

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