



Australian Government
Department of Health and Aged Care
 Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	317149	AA-Med Pty Ltd - Home seizure monitoring system
ARTG entry for	Medical Device Included Class IIa	
Sponsor	AA-Med Pty Ltd	
Postal Address	Suite 4 Level 10 1 Chandos Street, St Leonards, NSW, 2065 Australia	
ARTG Start Date	2/05/2019	
Product Category	Medical Device Class IIa	
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
Empatica SRL	Via Stendhal 36 , Milano, 20144 Italy

Products

1 . Home seizure monitoring system

Product Type	Single Device Product	Effective Date	2/05/2019
GMDN	61288 Home seizure monitoring system		
Intended Purpose	<p>The Embrace is a wearable device, worn on the wrist of a child or adult, for use in home or in professional healthcare environments. It senses electro dermal activity and motion data in order to detect patterns that may indicate a possible convulsive seizure in patients with epilepsy or at risk of having epilepsy. When a seizure event is detected, it sends a command to a paired wireless device that is programmed to initiate an alert (or send an alarm) to a designated caregiver.</p> <p>It is optimized to detect seizures involving electro dermal activity and motion patterns with a duration of at least 20 seconds. These characteristics are generally associated with tonic-clonic seizures. It doesn't detect every single generalized tonic-clonic seizure. It is not meant as substitute to seizure monitoring practices, but rather to serve as a supplement in expediting first-response time. It cannot detect complex partial seizures, absence seizures and non-convulsive seizures.</p>		

Specific Conditions

No Specific Conditions included on Record

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