Australian Government

Department of Health

Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	304681	Australasian Medical & Scientific Ltd - Infusion pump, insulin, ambulatory

ARTG entry for	Medical Device Included Class IIb
Sponsor	Australasian Medical & Scientific Ltd
Postal Address	PO Box 5197, WEST CHATSWOOD, NSW, 1515 Australia
ARTG Start Date	18/06/2018
Product Category	Medical Device Class IIb
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
Tandem Diabetes	11075 Roselle Street San Diego, CA, 92121 United States Of America

Products

1 . Infusion pump, insulin, ambulatory

Product Type	Single Device Product	**Effective Date**	18/06/2018
GMDN	35983 Infusion pump, insulin, ambulatory		
Intended Purpose	A portable insulin infusion pump, including sterile cartridge, that delivers insulin subcutaneously through a disposable infusion set.		

Specific Conditions

1. The hardware of the Device supplied in Australia must have a manufacturing date of 1 August 2020 or later; and

2. The software embedded within the Device supplied in Australia must be the software version Basal-IQ 6.4.1 or above; and

3. The Sponsor shall report all adverse events that occur in Australia to the TGA via the TGA reporting portal until 30 March 2022. The exemptions from reporting adverse events to the TGA set out on the TGA website: https://www.tga.gov.au/adverse-event-reporting, shall not apply to this condition.
The imposition of the condition takes effect on 30 March 2021.
Note: These conditions imposed on the kind of device are in addition to any other conditions imposed on the ARTG entry and conditions applying automatically under the Therapeutic Goods Act 1989 and Therapeutic Goods (Medical Devices) Regulations 2002.