



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry: 282772 Stryker Australia Pty Ltd - Non-rechargeable public automated external defibrillator

ARTG entry for Medical Device Included Class IIb
Sponsor Stryker Australia Pty Ltd
Postal Address PO Box 970, ARTARMON, NSW, 1570
Australia
ARTG Start Date 22/11/2016
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
Physio-Control Inc	11811 Willows Road NE Redmond, Washington, 98052 United States Of America

Products

1 . Non-rechargeable public automated external defibrillator

Product Type	Single Device Product	Effective Date	22/11/2016
GMDN	48047 Non-rechargeable public automated external defibrillator		
Intended Purpose	A portable electronic device intended for use by minimally trained responders to treat victims of sudden cardiac arrest. It is designed to automatically analyze electrical activity of the heart to determine whether a defibrillation pulse (shock) is required. If a shockable rhythm is detected, the device automatically delivers shocks through a pair of adhesive defibrillation electrodes on the victims chest. The electrodes serve both to monitor the ECG and to deliver the defibrillator discharges. The device is powered by a non- rechargeable battery and intended for public access environments		

Specific Conditions

No Specific Conditions included on Record

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