



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	228210	Stryker Australia Pty Ltd - Defibrillator, Fully-automated - 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	19/09/2014	
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
HeartSine Technologies Ltd	207 Airport Road West Belfast, Northern Ireland, BT3 9ED United Kingdom

Products

1 . Defibrillator, Fully-automated - Non-rechargeable public automated external defibrillator

Product Type	Medical device system	Effective Date	19/09/2014
GMDN	48047 Non-rechargeable public automated external defibrillator		
Intended Purpose	A portable electronic device designed to automatically detect cardiac arrhythmias (ventricular fibrillation/pulseless ventricular tachycardia) in a sudden cardiac arrest (SCA) patient, after which it automatically activates defibrillation of the heart through application of electrical shocks to the chest surface. It consists of an external pulse generator (EPG) with a cardiac rhythm recognition system and a pair of skin-adhesive electrodes to monitor the rhythm and deliver the shocks; it also includes a non-rechargeable battery for energy.		

Specific Conditions

No Specific Conditions included on Record

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