



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	156690	Stryker Australia Pty Ltd - Defibrillator, semi-automated
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	12/11/2008	
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, semi-automated

Product Type	Single Device Product	Effective Date	12/11/2008
GMDN	37805 Defibrillator, semi-automated		
Intended Purpose	A device that can analyse an electrocardiogram (ECG) to determine whether or not a defibrillator shock should be delivered. It is attached to the patient through a pair of adhesive defibrillation electrodes that serve both to monitor the ECG and to deliver the defibrillator discharges. The semi-automated defibrillator indicates to the operator when to deliver the shock.		

Specific Conditions

No Specific Conditions included on Record

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