TGA eBS

Record Summary

156690 Aero Healthcare - Defibrillator, semi-automated

Sponsor	Aero Healthcare
Therapeutic Type	Medical Device
Product Category/ Class	Included Class IIb
ARTG Start date	12/11/2008
Postal Address	PO Box 1635, ARMIDALE, NSW, 2350 Australia
Billing Address	PO Box 1635, ARMIDALE, NSW, 2350 Australia

Conditions

The automatic conditions applicable to the inclusion of all kinds of medical devices in the Register are as specified in section 41FN of the Therapeutic Goods Act 1989.

The standard conditions that are imposed under section 41FO of the Therapeutic Goods Act 1989 when kinds of medical devices are included in the Register are as set out in the following paragraphs.

For a medical device included in the Register under Chapter 4 and imported into Australia, the Sponsor must ensure that information about the Sponsor is provided in such a way as to allow the sponsor to be identified.

Each sponsor shall retain records of the distribution of all of the sponsor's medical devices included in the Register under Chapter 4. In the case of records relating to a Class AIMD medical device, Class III medical device, or Class IIb medical device that is an implantable medical device, the distribution records shall be retained for a minimum period of 10 years. In the case of records relating to any other device, the distribution records shall be retained for a minimum period of 5 years.

The sponsor of a medical device included in the Register under Chapter 4 shall keep an up to date log of information of the kind specified in Regulation 5.8.

It is a condition of inclusion in the ARTG that the sponsor of a medical device that is an AIMD, Class III or implantable Class IIb provides three consecutive annual reports to the Head of the Office of Devices, Blood and Tissues, Therapeutic Goods Administration following inclusion of the device in the ARTG. (as specified in 5.8 of the regulations) Annual reports are due on 1 October each year. Reports should be for the period 1 July to 30 June. The first report following the date of inclusion in the ARTG must be for a period of at least six months but no longer than 18 months. Subsequent reports are to be provided on 1 October for a further 2 years. The annual report must include all complaints received by the manufacturer relating to problems with the use of the device that have been received by them over the year.

Where a medical device included in the Register, contains a substance which is included in the Fourth Schedule to the Customs (Prohibited Imports) Regulations or the Eighth Schedule to the Customs (Prohibited Exports) Regulations the Sponsor shall, at the time of importation or exportation of the medical device, be in possession of a licence and a permission for importation or exportation of each consignment of the goods as required by those regulations.

A sponsor shall ensure that a medical device within their control is stored and transported in accordance with the instructions and information provided by the manufacturer.

Manufacturers

Name	Address	Certificate number(s)
HeartSine Technologies Limited	Canberra House 203 Airport Road West Belfast, Ireland, BT3 9ED Ireland	DV-20081007-MC-061403-11

Products

1.Defibrillator, semi-automated

Product Type	Single Device Product	**Status**	Current
		Effective date	12/11/2008

GMDN	37805 Defibrillator, semi-automated
Functional description	Not included on record
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.
Variant information	

Device Information

04 Electro mechanical medical devices

Specific Conditions

No Specific Conditions included on Record

Poison information

Poison Not recorded

Additional Product information

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