TGA eBS

Record Summary

228210 Aero Healthcare - Defibrillator, Fully-automated - Non-rechargeable public automated external defibrillator

Sponsor	Aero Healthcare
Therapeutic Type	Medical Device
Product Category	Included Class IIb
ARTG Start date	19/09/2014
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 Product Review, 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 and adverse events received by the manufacturer relating to problems with the use of the device that have been received by them over the year. For orthopaedic implant prosthesis that have been re-classified from Class IIb to Class III medical devices, annual report information must be submitted if the device meets either of the following criteria: I.The device was subject to a TGA application audit based on revision rate when the device transitioned from Class IIb to Class III; and/or II.No devices were supplied to the Australian marketplace before 30 June 2012. As per the standard automatic condition, annual reports should be submitted each year for the first three years of inclusion as a Class III medical device on the ARTG.,

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, Fully-automated - Non-rechargeable public automated external defibrillator

Product Type	Medical device system	**Status**	Current
		Effective date	19/09/2014

GMDN	48047 Non-rechargeable public automated external defibrillator
Functional description	Not included on record
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.
Variant information	

Device Information

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Specific Conditions

No Specific Conditions included on Record

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