



Australian Government

Department of Health and Ageing
Therapeutic Goods Administration

Australian Register of Therapeutic Goods Certificate

Issued to

AMBU Australia Pty Ltd

for approval to supply

AMBU Australia Pty Ltd - Suction unit, transportable

ARTG Identifier: 168573 Class 1
ARTG Start date: 2/02/2010
Product Category: Medical Device Included Class 1
GMDN: 36616
GMDN Term: Suction unit, transportable
Intended Purpose: Intended to provide a negative pressure to allow secretions/fluids to be removed from the body. This device is transportable

Table with 3 columns: Manufacturer Details, Address, Certificate number(s). Row 1: Ambu AS, Baltorpbakken 13, Ballerup, , DK-2750, Denmark

ARTG Standard Conditions

The above Medical Device Included Class 1 has been entered on the Register subject to the following 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.
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.
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.

Products covered by this Entry

- 1. Suction unit, transportable

Product Specific Conditions

No specific conditions have been recorded against this entry.

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