



Australian Government

Department of Health and Ageing  
Therapeutic Goods Administration

# Australian Register of Therapeutic Goods Certificate

Issued to

**Ical & Trading Co**

for approval to supply

## Ical & Trading Co - Emergency kit, first aid, reusable, non-medicated

<b>ARTG Identifier</b>	200318 Class Is
<b>ARTG Start date</b>	24/08/2012
<b>Product Category</b>	Medical Device Included Class Is
<b>Intended Purpose</b>	<p>First Aid Kits in a Nylon bag which fits easily on a shelf or in a confined space such as under a car seat. When unzipped, the contents are still protected from the ground whilst the first aider can easily see and search for particular contents.</p> <p>Nylon bag size approx. 25cmLx16cmHx13cmW</p> <p>Wound bandage /plaster: 19mmx72mm: Sterile non-stick strip, for dressing a cut, wound</p> <p>Wound dressing: 10cmx20cm: combined dressing and bandage</p> <p>Sterile gauze sponge: 7.5xcmx7.5cm, 10cmx10cm: cleaning and prepping light-to moderately draining wounds</p> <p>Elastic bandage: 5cmx4m, 7.5cmx4m, 10cmx4m: bandage of stretchable fabric that provides support and allows movement. Among its uses is application to swollen extremities, such as knees or wrists, varicose veins and broken ribs.</p> <p>First aid bandage: 6cmx8cmx4.5m, 8cmx10cmx4.5m, 10cmx12cmx4.5m, 7.5cmx3.2m; all with pad 18cmx25cm: confirming bandage is made of PBT elastic bandage and dressing pad. It is more easier and quicker to treat the wound care since the dressing pad is already stick to PBT elastic bandage.</p>

Manufacturer Details	Address	Certificate number(s)
Davemed Healthcare Co Ltd	No 87 Yi Le Tang Industry Area Yangbu Town Wucheng District Jinhua City, Zhejiang Province, 321000 China - Peoples Republic of	DV-2012-MC-07396-3

### ARTG Standard Conditions

The above Medical Device Included Class Is 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. 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.

### **Products Covered by This Entry**

#### **1. Emergency kit, first aid, reusable, non-medicated**

#### **Product Specific Conditions**

No specific conditions have been recorded against this entry.

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