



# ARTG Certificate

Issued to

**Store Holdings Pty Ltd**

for approval to supply

**STORE HOLDINGS P/L - Compress, <specify>**

ARTG Identifier **120115 Class 1**  
ARTG Start date **27/06/2005**  
Product Category: **Medical Device Included Class 1**  
GMDN **34969**  
GMDN Description **Compress, <specify>**  
Intended Purpose **Intended to ease pain and swelling to soft tissue injuries when applied externally.**

## 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. 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.
- The sponsor shall provide to the Director, Office of Devices, Blood and Tissues, Therapeutic Goods Administration, three consecutive reports which include information of a kind specified in Regulation 5.8 that arises during the reporting period, concerning Class III, Class AIMD or implantable Class IIb medical devices. The reporting period for the first report commences on the date of inclusion and is to be at least a period of six months but not more than 18 months ending on 1 October. For subsequent reports the reporting period is 12 months ending on 1 October.
- 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. Compress, <specify>

#### Product Specific Conditions

No specific conditions have been recorded against this entry.

#### Product Standard Indications

No standard indications have been recorded against this entry.

#### Product Specific Indications

No specific indications have been recorded against this entry.

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END OF CERTIFICATE

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ARTG Certificate



**Australian Government**  
**Department of Health and Ageing**  
**Therapeutic Goods Administration**

**CERTIFICATE OF FREE SALE**  
**FOR THE MINISTRY OF HEALTH, UNITED KINGDOM**

**Certificate Number: 05/847A**

**Products:** Medichill Ice Pads  
Medichill Cohesive Bandage

**GMDNS codes:** 34969

**Sponsor:** Store Holdings Pty Ltd  
Unit 113 Westpoint Centre  
396 Scarborough Beach Road  
Osborne Park  
Western Australia 6017

The above product(s) are included on the Australian Register of Therapeutic Goods (ARTG) under the Australian Register of Therapeutic Goods Number **ARTG number 120115** and as such are available for free sale in Australia and for export from Australia by the Sponsor.

The Sponsor has provided a Declaration to the Therapeutic Goods Administration that devices of that kind comply with the Essential Principles.



  
Department of  
**Health and  
Ageing**

Michael Flood  
Delegate of the Secretary  
Office of Devices, Blood and Tissues

21st September 2005

Our Ref: CA 009696

**Mr Paul Maynard**  
Medichill UK Ltd  
1a Cooperage Green  
Royal Clarence Yard  
Weevil Lane  
Gosport, Hampshire  
PO12 1AX  
United Kingdom

11 May 2007

Dear Mr Paul Maynard,

**MEDICAL DEVICES REGULATIONS 2002: REGULATION 19**  
**Registration of Persons Placing General Medical Devices on the Market**

Thank you for informing the Competent Authority of the details of **Manufacturers Name:- Thermasorb Pty Ltd** located at **Manufacturers Address:- 9b Merola Way Campbellfield Victoria 3061 Australia** for whom you are acting as the authorised representative and for supplying the medical device information.

Your registration has been recorded based on your declaration that you have determined that the device(s) fall within the definition of "medical device", and that you have classified it/them as falling within Regulation 19 taking into account the intended purpose(s) and mode(s) of action. In accepting your registration, I should make clear that the Competent Authority does not examine each individual notification and therefore cannot and does not necessarily endorse these determinations. Neither does this letter represent any form of accreditation or approval by the UK Competent Authority.

Your registration is based upon your declaration on the RG2 form and means that:

**For Manufacturers of Class I medical devices, Assemblers, and Sterilisers**

You should now be operating under the Medical Devices Directive and the above Regulations for the products you asked us to register, by fully complying with the essential requirements, CE marking those products or labelling them as such.

**For Manufacturers of Custom-made devices**

You should be ready to claim compliance with the Directive and Regulations and should be manufacturing custom-made devices in accordance with their requirements.

**If you stop placing devices on the market or if you are not complying with the Regulations you should inform us so that we can amend our records. You should be aware that it is an offence to place on the market CE marked devices that do not comply with the regulations.**

The information you provided has been recorded against the reference number shown at the top of this letter, which we ask you to quote in all future correspondence and communications.

**Please inform us of any changes to:**

- the company information
- additional generic groups of devices (not individual products within an existing generic group)
- discontinuation of a generic group of devices.

Please use RG2, the Registration form, to tell us about any of these changes.

Thank you for registering the following generic groups of devices:

***Class I Devices:***

***Medichill Ice Pads***  
***Medichill Cohesive Bandages***  
***Medichill Gel Packs***  
***Medichill Instant Ice Packs***

***Custom Made Devices:***

***None***

***Products Covered By Article 12:***

***None***

Should you have any queries regarding your registration please do not hesitate in contacting us.

Yours sincerely



Sean Williams  
Regulatory Affairs Administrator

Tel: 0207 084 3325

Fax: 0207 084 3107

Email: [sean.williams@mhra.gsi.gov.uk](mailto:sean.williams@mhra.gsi.gov.uk)



## REGULATORY INFORMATION

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### Medical Device Notification

#### Confirmation

This is to confirm that details of the following device have been emailed to Medsafe.

WAND Reference: 081215-WAND-65V4G2  
Sponsor's own reference: Medichill Ice Pads  
GMDN:

Medsafe recommends that you print and keep a copy of this confirmation as a record of your notification. This confirmation may be used as proof of notification for prospective customers.

Notifications made using the interim process before implementation of the new system in February 2009 will not be viewable online.

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