

REGISTRATION DETAILS

ARTG Number: 121081 The Critical Group Pty Ltd - Suture, polypropylene, barbed
Sponsor: 1220 The Critical Group Pty Ltd
Agent: 19351 Regulatory Concepts Pty Ltd

ARTG Category: Included **ARTG Start Date:** 3/08/2005
Type of Therapeutic Good: Included Medical Device
Approval Area: Medical Devices

SPONSOR DETAILS

Postal Address: PO Box 6466
 BAULKHAM HILLS BUSINESS CENTRE
 NSW
 2153
 Australia
Effective Date: 3/08/2005

Formulation Confidential from Sponsor: N
Manufacturer Confidential from Sponsor: N

AGENT DETAILS

Postal Address: Unit 9 7 Anella Avenue
 CASTLE HILL
 NSW
 2154
 Australia
Effective Date: 3/08/2005

Formulation Confidential from Agent: N
Manufacturer Confidential from Agent: N

ARTG STATUS

ARTG Status: Current **ARTG Start Date:** 3/08/2005
Status Effective Date: 3/08/2005 **Charge Effective Date:** 3/08/2005
Changed By: APPSCBR06
Device: Y **Medicine:** N **OATD:** **Code Stock:** **Created By:** ELF: N

CONDITIONS**Standard 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. (60)

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. (61)

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. (62)

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. (63)

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. (64)

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. (65)

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. (66)

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. (67)

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Charge Level: Included Medical Device **Charge Effective Date:** 3/08/2005
Class IIb Annual Charge

Invoice Status: N

Renewal Date: 15/10/2005

PRODUCT DETAILS

1. The Critical Group Pty Ltd - Suture, polypropylene, barbed **ID:**
Product Type: Single Device Product 202918

PRODUCT STATUS

Product Status: Current **Product Status Date:** 3/08/2005
Changed By: APPSCBR06

SUPPLY INFORMATION

Supplied Overseas: N **Supplied in Australia:** Y

STERILITY

Sterile: Yes

COMPONENT DETAILS

1. Medical Device Component

DETAILS

Component ARTG Id: 151521

PRODUCT REFERENCE & TGAIN DETAILS

1. **App. Eval. Number:** (No Evaluation #)
- | ELF Number | ELF Source | ELF Status | ELF Status Date | DEAL Appl # | TGAIN |
|------------|------------|------------|-----------------|-------------------------|-------|
| - | - | - | - | DV-20050301-DA-000632-1 | 632 |
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CURRENT MANUFACTURER DETAILS

1. SURGICAL SPECIALTIES CORPORATION **ID:** 9687
100 Dennis Drive
Reading **Active Start Date:**
190606 3/08/2005

United States Of America

Evidence Name: Surgical Specialties for CA
Evidence Number: GB01/53650
Issued Date: 8/11/2001
Expiry Date: 8/11/2008
Evidence Issued Under: 02
Annex Route: Schedule 3 Part 1 (Annex II)
Notified Body: SGS United Kingdom Limited [0120]
Notified Body File Ref: SGS CE 01 0303
