

### **Australian Government**

# **Department of Health and Aged Care**

Therapeutic Goods Administration

### **Public Summary**

Summary for ARTG Entry: 132509 Johnson & Johnson Medical Pty Ltd - J&J Intl ULTRAPRO Hernia System - Mesh, polymeric, composite

ARTG entry for Medical Device Included Class III

Sponsor Johnson & Johnson Medical Pty Ltd

Postal Address PO Box 134, NORTH RYDE BC, NSW, 1670

ustralia

ARTG Start Date 24/10/2006

Product Category Medical Device Class III

Status Active

Approval Area Medical Devices

### Conditions

- The inclusion of the kind of device in the ARTG is subject to compliance with all conditions placed or imposed on the ARTG entry. Refer Part 4-5, Division 2 (Conditions) of the Therapeutic Goods (Medical Devices) Regulations 2002 for relevant information.
- Breaching conditions of the inclusion related to the device of the kind may lead to suspension or cancellation of the ARTG entry; may be a criminal offence; and civil penalties may apply.

#### Manufacturers

Name Address

Johnson & Johnson International c/o European Logistics Centre

Leonardo Da Vincilaan 15 , Diegem, BE-1831

Belgium

#### Products

## 1. J&J Intl ULTRAPRO Hernia System - Mesh, polymeric, composite

Product Type Medical device system Effective Date 24/10/2006

**GMDN** 44756 Abdominal hernia surgical mesh, composite-polymer

Functional A pre-shaped, partially absorbable three-dimensional device contructed of an undyed onlay patch connected by a mesh cylinder to

**Description** an underlay patch reinforced by a flat undyed absorbable film of MONOCRYL

Intended Purpose For open repair of abdominal wall hernia defects

Variant information Shape - round and oval

Size (cm) underlay diameter 7.5-12

### **Specific Conditions**

No Specific Conditions included on Record

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