



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry: 197042 Australian Medical Products & Services AMPS Pty Ltd - Penile traction splint

ARTG entry for Medical Device Included Class 1
Sponsor Australian Medical Products & Services AMPS Pty Ltd
Postal Address PO Box 2509, MELBOURNE, VIC, 3000
Australia
ARTG Start Date 30/04/2012
Product category Medical Device Class 1
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 Act 1989 and Part 5, Division 5.2 (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

DanaMedic Aps

Address

Maglebjergvej 4
Lyngby, , DK 2800
Denmark

Products

1. Penile traction splint

Product Type Single Device Product **Effective date** 30/04/2012

GMDN 46340 Penile traction splint

Intended purpose Traction Device for the purpose of enlarging the shaft of the penis.

Specific Conditions

No Specific Conditions included on Record

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