



**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
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**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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Public Summary