



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	168962	Platigo Solutions Pty Ltd - Penile foreskin stretching kit
ARTG entry for	Medical Device Included Class 1	
Sponsor	Platigo Solutions Pty Ltd	
Postal Address	PO Box 567, ROSEVILLE, NSW, 2069 Australia	
ARTG Start Date	11/02/2010	
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	Address
Platigo Solutions Pty Ltd	329B Eastern Valley Way CASTLE COVE, NSW, 2069 Australia

Products

1 . Penile foreskin stretching kit

Product Type	Procedure Pack	Effective Date	11/02/2010
GMDN	52752 Penile foreskin stretching kit		
Intended Purpose	A collection of devices intended to be operated by a patient at home to stretch the foreskin of the penis to treat phimosis (tightening of the foreskin) or to preferentially develop a looser foreskin. It typically consists of a balloon assembly, an inflator, cotton buds, insertion rods, and alcohol cleaning swabs. The inflatable balloon is inserted through the natural opening of the foreskin and positioned between the glans penis and the foreskin and inflated. This procedure is typically performed daily for a period (e.g., 14 days) to gradually stretch the foreskin. This is a single-patient device reapplied to the patient over a short term (single-use) before being discarded.		

Specific Conditions

No Specific Conditions included on Record

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