



Australian Government
Department of Health
Therapeutic Goods Administration

Australian Register of Therapeutic Goods Certificate

Issued to

Compliance Management Solutions

for approval to supply

Compliance Management Solutions - Penile traction splint

ARTG Identifier	365771
ARTG Start Date	13/05/2021
Product Category	Medical Device Included Class 1
GMDN	46340
GMDN Term	Penile traction splint
Intended Purpose	Andropenis and Andropeyronie is a mechanical medical device worn on the penis for gradual penile lengthening, treatment of penile curvature, treatment of acute and chronic phase of Peyronies disease. It is also used to create or maintain sufficient penile rigidity for sexual intercourse.

Manufacturer Details	Address	Certificate number(s)
Andromedical SL	Gran Via 6 4th , Madrid , 28013 Spain	

ARTG Standard Conditions

The above Medical Device Included Class 1 has been entered on the Register subject to the following 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.

Products Covered by This Entry

1. Penile traction splint

Product Specific Conditions

No specific conditions have been recorded against this entry.

Therapeutic Goods Administration
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