

TGA
THERAPEUTIC GOODS ADMINISTRATION

Device Application

[Help](#)

Close

Create Variation

Clone

Date Received : 07/08/2008

Status : Approved

ARTG ID 154288

Application Details

Application Identifier:

DV-20080703-DA-058082-11

Sponsor's own Reference:

Andromedical_Andropenis_ClassI

Application For:

Medical Device - Included

Sponsor Details

Sponsor Name:

Emergo Asia Pacific Pty Ltd

Contact Details:

Rene van de Zande

Class Details

Class:

Class 1

Intended Purpose of use:

The Andropenis® is intended for correction of penile curvatures without surgery, treatment of Peyronie's Disease, as well as post surgical treatment of penile lengthening surgery, and after plastic and reconstructive surgeries of the penis.

Specific Detatils

Is the device, or any form of the device, supplied sterile:

No

Sterilisation Method:

Is the device intended to be invasive:

No

Is the device, or any form of the device, intended for single use:

No

Is the device an active device:

No

Does the device contain material or ingredients of microbial origin:

No

Does the device contain material or ingredients of recombinant origin:

No

Does the device contain material or ingredients manufactured or formulated using a genetically modified organism:

No

Does the device contain material or ingredients of Animal Origin rendered non-viable:

No

Animal Species:

Country of Origin:

Does the device contain material or ingredients of Human Origin:

No

Does the device contain Human Blood or its components: No
 Does the device consist of: Single product only
 Is the device medicated: No
 Is the device formulated: No
 Does the product contain a medicine that is supplied separately in the Australian Market: No
 Does the product contain a medical device which incorporates a medicine as an integral part and that has an action ancillary to the device: No

Manufacturer Details

Manufacturer Name: Andromedical SL (Spain)[50712]
 Manufacturer Address: Calle Procion 7 Madrid 28023 Spain S [167387]
 New Manufacturer Name: Andromedical, S.L.
 New Manufacturer Address: C/ Procion, 7, 28023, Madrid
 New Manufacturer Country: Spain

GMDNS Code and description

GMDNS Code and Description: Penile traction splint[46340]

Payment Information

Payment Type:

Start Dates

Application Received
 Application Received
 Payment Received

Finish Dates

07/08/2008 Payment Received
 07/08/2008 Application Approved
 07/08/2008 Application Approved

Working Days

07/08/2008 0
 07/08/2008 19
 08/04/2008