



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry: 370310 MHDU Operations Pty Ltd - PeniMasterPro - Penile traction splint

ARTG entry for Medical Device Included Class 1

Sponsor MHDU Operations Pty Ltd

Postal Address PO Box 63, Deakin, ACT, 2600
Australia

ARTG Start Date 28/06/2021

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
MSP Concept GmbH & Co KG	Dusseldorfer Str 70 A , Berlin, D-10719 Germany

Products

1 . PeniMasterPro - Penile traction splint

Product Type	Single Device Product	Effective Date	28/06/2021
--------------	-----------------------	----------------	------------

GMDN 46340 Penile traction splint

Intended Purpose A mechanical device worn on the penis typically for gradual penile lengthening or for the non-surgical correction of penile curvature (Peyronie's disease).

Specific Conditions

No Specific Conditions included on Record

© Commonwealth of Australia. This work is copyright. You are not permitted to re-transmit, distribute or commercialise the material without obtaining prior written approval from the Commonwealth. Further details can be found at <http://www.tga.gov.au/about/website-copyright.htm>.

Public Summary