



**Australian Government**  
**Department of Health and Aged Care**  
Therapeutic Goods Administration

**Public Summary**

<b>Summary for ARTG Entry:</b>	463110	AquaUtopia Pty Ltd T/A The UniqueHorn Company - Assistive sexual erection device
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<b>ARTG entry for</b>	Medical Device Included Class 1
<b>Sponsor</b>	AquaUtopia Pty Ltd T/A The UniqueHorn Company
<b>Postal Address</b>	PO Box 5055, Manly, QLD, 4179 Australia
<b>ARTG Start Date</b>	30/09/2024
<b>Product Category</b>	Medical Device Class 1
<b>Status</b>	Active
<b>Approval Area</b>	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
AMEC Plastics	35 Harrington Street Arundel, QLD, 4214 Australia

**Products**

**1 . Assistive sexual erection device**

<b>Product Type</b>	Single Device Product	<b>Effective Date</b>	30/09/2024
<b>GMDN</b>	43245 Assistive sexual erection device		
<b>Intended Purpose</b>	A device to assist in the rehabilitation of the penis, and to enable erections suitable for penetration		

**Specific Conditions**

No Specific Conditions included on Record

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