Public Summary

Summary for ARTG Entry: 118548
Fresenius Medical Care Australia Pty Ltd - AquaWTU, AquaUNO, AquaB, AquaB DUO, Genius Aquator, AquaPlus, Aquasafe08, Aquastore08, AquaHWCS, etc - Water purification unit, reverse osmosis

ARTG entry for Medical Device Included Class IIb
Sponsor Fresenius Medical Care Australia Pty Ltd
Postal Address Level 27/100 Miller Street, North Sydney, NSW, 2060 Australia
ARTG Start Date 18/04/2005
Product Category Medical Device Class IIb
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 Fresenius Medical Care AG & Co KGaA
Address Else Krone Strasse 1
Bad Homburg, Bad Homburg, D-61352 Germany

Products

1. AquaWTU, AquaUNO, AquaB, AquaB DUO, Genius Aquator, AquaPlus, Aquasafe08, Aquastore08, AquaHWCS, etc - Water purification unit, reverse osmosis

<table>
<thead>
<tr>
<th>Product Type</th>
<th>Effective Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medical device system</td>
<td>18/04/2005</td>
</tr>
</tbody>
</table>

GMDN 35434 Water purification unit, reverse osmosis

Intended Purpose To purify water for use in dialysis machines

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.