### Summary for ARTG Entry: 97288

**Medical Specialties Australasia Pty Ltd - Mesh, surgical**

**ARTG entry for**
Medical Device Included Class IIb

**Sponsor**
Medical Specialties Australasia Pty Ltd

**Postal Address**
PO Box 764, WILLOUGHBY, NSW, 2068
Australia

**ARTG Start Date**
29/09/2003

**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**
pfm medical titanium GmbH

**Address**
Sudwestpark 42
. Nurnberg, 90449
Germany

### Products

**1. Mesh, surgical**

<table>
<thead>
<tr>
<th>Product Type</th>
<th>Effective Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Single Device Product</td>
<td>29/09/2003</td>
</tr>
</tbody>
</table>

**GMDN**
16048 Mesh, surgical

**Intended Purpose**
Soft tissue support

<table>
<thead>
<tr>
<th>Exception(s) to approval</th>
<th>Start</th>
<th>Exception product description</th>
<th>Reason</th>
<th>Notification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Active</td>
<td>12/08/2015</td>
<td>TILOOP Tape, TILOOP Two, TILOOP Total 4, TILOOP Total 6, TILOOP Fix, TILOOP Mesh, TILOOP Patch, TILOOP Clip</td>
<td>Product excluded by regulatory activity</td>
<td>The Secretary is satisfied that the safety and performance of a device included in the entry are unacceptable. However, as other devices of the same kind are included under the ARTG entry, the entry has been varied to exclude these devices.</td>
</tr>
</tbody>
</table>

### Specific Conditions

No Specific Conditions included on Record

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