### Public Summary

**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>

**GMON**  
16048 Mesh, surgical

**Intended purpose**  
Soft tissue support

**Exception(s) to approval**  
Active 12/08/2015

<table>
<thead>
<tr>
<th>Exception start date</th>
<th>Exception product description</th>
<th>Reason</th>
<th>Notification</th>
</tr>
</thead>
<tbody>
<tr>
<td>12/08/2015</td>
<td>TILOOP Tape</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>

| TILOOP Two
| TILOOP Total 4
| TILOOP Total 6
| TILOOP Fix
| TILOOP Mesh
| TILOOP Patch
| TILOOP Clip |

**Specific Conditions**  
No Specific Conditions included on Record

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