



**Australian Government**  
**Department of Health**  
 Therapeutic Goods Administration

**Public Summary**

<b>Summary for ARTG Entry:</b>	135045	Ossur Australia Pty Ltd - Orthosis, arm, wrist/hand, unit
<b>ARTG entry for</b>	Medical Device Included Class 1	
<b>Sponsor</b>	Ossur Australia Pty Ltd	
<b>Postal Address</b>	26 Ross Street, NORTH PARRAMATTA, NSW, 2151 Australia	
<b>ARTG Start Date</b>	19/02/2007	
<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**

<b>Name</b>	<b>Address</b>
Ossur Hf	27412-A Laguna Hills Drive ALISO VIEJO, CALIFORNIA, 92656 United States Of America

**Products**

**1. Orthosis, arm, wrist/hand, unit**

<b>Product Type</b>	Single Device Product	<b>Effective date</b>	19/02/2007
<b>GMDN</b>	41459 Orthosis, arm, wrist/hand, unit		
<b>Intended purpose</b>	This is an orthosis that encompassess the wrist joint and the hand. The device is body worn.		

**Specific Conditions**

No Specific Conditions included on Record

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