



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

**Public Summary**

**Summary for ARTG Entry:** 284127 Ossur Australia Pty Ltd - Cervical spine immobilization system, single-use

**ARTG entry for** Medical Device Included Class IIb  
**Sponsor** Ossur Australia Pty Ltd  
**Postal Address** 26 Ross Street, NORTH PARRAMATTA, NSW, 2151  
 Australia  
**ARTG Start Date** 3/01/2017  
**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**

<b>Name</b>	<b>Address</b>
Ossur HF	5 Grjothals , Reykjavik, IS-110 Iceland

**Products**

**1. Cervical spine immobilization system, single-use**

<b>Product Type</b>	<b>Effective date</b>
Single Device Product	3/01/2017

**GMDN** 60367 Cervical spine immobilization system, single-use  
**Intended purpose** For use with the ReSolve Halo Vest in traumatic or chronic disorders requiring traction along the cervical spine to align the vertebral structures (reduce deformities), maintain reduction, or provide stabilization. Indications include cervical spine trauma or surgery.

**Specific Conditions**

No Specific Conditions included on Record

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