



Australian Government
Department of Health
 Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry: 283346 Ossur Australia Pty Ltd - Cervical spine immobilization system, single-use

ARTG entry for Medical Device Included Class 1
Sponsor Ossur Australia Pty Ltd
Postal Address 26 Ross Street, NORTH PARRAMATTA, NSW, 2151
 Australia
ARTG Start Date 9/12/2016
Product category Medical Device Class 1
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	Address
Ossur HF	5 Grjothals , Reykjavik, IS-110 Iceland

Products

1. Cervical spine immobilization system, single-use

Product Type	Effective date
Single Device Product	9/12/2016

GMDN 60367 Cervical spine immobilization system, single-use

Intended purpose Orthopaedic device designed to immobilise the cervical spine (the bones in the neck) after an injury or surgery, to protect the bones from damaging movement during the healing processes. For use 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. A frame that encompasses the whole or part of the cervical region including the head. The device is body worn.

Specific Conditions

No Specific Conditions included on Record

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