



Australian Government
Department of Health
 Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry: 284128 Ossur Australia Pty Ltd - Traction system skull tongs

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

Name	Address
Ossur HF	5 Grjothals , Reykjavik, IS-110 Iceland

Products

1. Traction system skull tongs

Product Type	Single Device Product	Effective date	3/01/2017
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GMDN 46528 Traction system skull tongs
Intended purpose Orthopaedic device in the form of a u-shaped frame secured to the patient's head using pins to provide traction to the cervical spine by applying longitudinal force from a traction system. Used in the management/treatment of damage to the cervical spine, aligns vertebral structures and provides stabilisation for a cervical spine injury caused by trauma or disease.

Specific Conditions

No Specific Conditions included on Record

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