



Australian Government

Department of Health
Therapeutic Goods Administration

Australian Register of Therapeutic Goods Certificate

Issued to

Ossur Australia Pty Ltd

for approval to supply

Ossur Australia Pty Ltd - Orthosis, <specify>

ARTG Identifier	346431
ARTG Start Date	22/10/2020
Product Category	Medical Device Included Class 1
GMDN	35218
GMDN Term	Orthosis, <specify>
Intended Purpose	Body worn orthoses such as supports, slings, braces, splints, stirrups, footwear for treatment, alleviation of, prevention, or compensation for, an injury or disability including support, stability, protection, compression, immobilisation, restriction of motion, realignment, offloading, reducing pressure, reducing slippage, maintaining, guiding and/or changing positions or movements. May also support treatment/healing of an injury, postoperatively, preoperatively, for recuperation, rehabilitation, recovery, deformities, fractures, sprains, strains, dislocations, soft tissue injuries, may be used for postural support and/or improving user's posture, relief of the geriatric or insensitive foot, may be intended for pain relief. Depending on the specific orthosis may be used on body parts and joints such as foot, ankle, spine, cervical spine, wrist, thumb, elbow, shoulder, arm, knee, hip.

Manufacturer Details	Address	Certificate number(s)
Anatomical Concepts Inc	1399 E Western Reserve Road Poland , OH , 44514-3250 United States Of America	

ARTG Standard Conditions

The above Medical Device Included Class 1 has been entered on the Register subject to the following 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.

Products Covered by This Entry

1. Orthosis, <specify>

Product Specific Conditions

No specific conditions have been recorded against this entry.

