



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, leg, ankle/foot, unit**

<b>ARTG Identifier</b>	336016
<b>ARTG Start Date</b>	8/05/2020
<b>Product Category</b>	Medical Device Included Class 1
<b>GMDN</b>	36206
<b>GMDN Term</b>	Orthosis, leg, ankle/foot, unit
<b>Intended Purpose</b>	Orthosis for use in grade II/III ankle sprain, stable fracture of the fibula, talus, calcaneus and medial malleolus, post ligament, soft tissue and tendon surgery, forefoot or midfoot injury. This is an orthosis that encompasses the ankle joint and the whole or part of the foot and is used as support for ankle and /or foot joints that have been injured.

Manufacturer Details	Address	Certificate number(s)
E-Life International Co Ltd	7F No 1 Baosheng Road Yonghe District , New Taipei City , 234 Taiwan	

## 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, leg, ankle/foot, unit

## Product Specific Conditions

No specific conditions have been recorded against this entry.

Therapeutic Goods Administration  
PO Box 100, Woden ACT 2606 Australia  
Phone: 1800 020 653  
Email: info@tga.gov.au

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