



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 - Transfemoral prosthesis socket

ARTG Identifier	325341
ARTG Start Date	23/10/2019
Product Category	Medical Device Included Class 1
GMDN	41156
GMDN Term	Transfemoral prosthesis socket
Intended Purpose	An externally-worn device designed to fit over the terminal end of a residual lower limb after amputation between the hip and knee joints (transfemoral), to act as the weight-bearing component and the point of attachment for the external prosthetic limb. Above knee socket, acts as part of the interface for attaching prosthetic components of the prosthetic leg to the amputee and intended to transfer weight bearing forces from the surface of the residual limb to a prosthetic limb. Non-invasive, reusable, for single patient use.

Manufacturer Details	Address	Certificate number(s)
Ossur HF	Grjothals 1-5 Reykjavik , Iceland , 110 Iceland	

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. Transfemoral prosthesis socket

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

ARTG Identifier: 325341
ARTG Start Date: 23/10/2019