



Australian Government
Department of Health
Therapeutic Goods Administration

Therapeutic Goods Act 1989
Approval under section 42DF for use of restricted representations by
Ossur Australia Pty Ltd

I, Rowena Love, Delegate of the Secretary to the Department of Health, on receipt of an application from Ossur Australia Pty Ltd, have approved under section 42DF of the *Therapeutic Goods Act 1989* (the Act) the restricted representations described in paragraph (a) (i) – (ii) below for use in advertisements directed to consumers, for the product identified in paragraph (b):

- a) (i) Representations which refer to "osteoarthritis" to the effect of providing accurate, balanced and contemporary information, the purpose of which is to inform consumers of the description of the disease; and
(ii) Representations which refer to "osteoarthritis" to the effect that the use of the devices may:
- provide symptomatic relief of knee osteoarthritis by bracing and/or supporting and/or stabilising and/or unloading the knee*
 - relieve joint pain associated with knee osteoarthritis by bracing and/or supporting and/or stabilising and/or unloading the knee*
 - improve knee joint function associated with osteoarthritis by bracing and/or supporting and/or stabilising and/or unloading the knee*

*while being worn (with the words 'while being worn' prominently displayed or communicated i.e. standing out so as to be easily read from a normal viewing distance and/or heard and understood).

- b) "Orthosis, leg, knee unit (unloading knee braces)" (ARTG No. 135047)

Dated this 14th day of March 2019

Signed electronically

Rowena Love
Delegate of the Secretary to the Department of Health
Advertising Compliance Unit
Regulatory Practice, Education and Compliance Branch