



**Australian Government**  
**Department of Health**  
Therapeutic Goods Administration

**Therapeutic Goods Act 1989**  
**Approval under section 42DF for use of restricted representations by**  
**DJO Global Pty Ltd**

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

- A:
- (i) Representations which refer to ‘diabetes’ to the effect: ‘Dr Comfort footwear is suitable for people living with diabetes’;
  - (ii) Representations which refer to ‘diabetes’ to the effect: ‘Dr Comfort footwear may assist in the prevention of foot complications which can be associated with diabetes’; and
  - (iii) Representation which refer to ‘diabetes’ and ‘diabetic foot complications/disease’ in the context of providing accurate, balanced and contemporary statistical information consistent with the body of scientific knowledge about the prevalence of diabetic foot disease in Australia \*

\*required balance to be achieved:

- (a) by not stating or in any way implying the use of the Devices is the only, or the predominant, way to manage or reduce risk of diabetic foot disease.
- (b) The statistics are presented in association with the need for an individual diabetes management plan, developed and managed by a medical practitioner.

B: Orthosis, footwear, orthopaedic, shoe (ARTG 204014)

Dated this 20<sup>th</sup> day of March 2019

*Signed electronically*

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