



Australian Government

Department of Health and Ageing
Therapeutic Goods Administration

Therapeutic Goods Act 1989

Approval under section 42DF for use of a restricted representation by
BMedical Pty Ltd

I, Dr Jane Cook, Head, Office of Product Review, Therapeutic Goods Administration and delegate of the Secretary to the Department of Health and Ageing, on receipt of an application by BMedical Pty Ltd, have approved under section 42DF (1) of the *Therapeutic Goods Act 1989* (the Act) the restricted representation described in paragraph (a) below for use in advertisements directed to consumers, for the products identified in paragraph (b) provide the condition in paragraph (c) is met:

(a) "Obstructive Sleep Apnoea/Apnea" (OSA)

(b) "Provent Therapy Nasal EPAP" – ARTG No. 186646

(c) all advertisements containing the representation "obstructive sleep apnoea" must contain the following advice, prominently displayed – 'This product must only be used on the advice of the medical practitioner treating your obstructive sleep apnoea.' (or words to that effect).

Dated this 7 day of September 2012

Dr Jane Cook
Delegate of the Secretary to the Department of Health and Ageing; and
Head
Office of Product Review