



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

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

I, Jane Cook, Office Head, Office of Product Review, Therapeutic Goods Administration and delegate of the Secretary to the Department of Health, on receipt of an application by Luxottica Retail Australia Pty Ltd, have approved under section 42DF (1) of the *Therapeutic Goods Act 1989* (the Act) the restricted representations described in paragraph (a) below for use in advertisements directed to consumers, for the product identified in paragraph (b), provided the conditions in paragraphs (c) and (d) are met:

- (a) "serious eye diseases", "vision threatening conditions", "glaucoma", "macular degeneration", "retinal changes that may be associated with diabetes" and "diabetic retinopathy";
- (b) "Interferometer - ophthalmic" device (ARTG Number 139387);
- (c) The use of the restricted representations identified in paragraph (a) must be limited to representing the product identified in paragraph (b) as an aid (or words to that effect) in the detection and monitoring of "serious eye diseases", "vision threatening conditions", "glaucoma", "macular degeneration", "retinal changes that may be associated with diabetes" and/or "diabetic retinopathy"; and
- (d) The product identified in paragraph (b) is not to be represented in any way to be for the diagnosis, treatment or follow up control of "serious eye diseases", "vision threatening conditions", "glaucoma", "macular degeneration", "retinal changes that may be associated with diabetes" or "diabetic retinopathy".

Dated this 14 day of October 2013

Jr Jane Cook  
Delegate of the Secretary to the Department of Health;  
Office Head  
Office of Product Review