



Australian Government

Department of Health
Therapeutic Goods Administration

Therapeutic Goods Act 1989

**Notification under section 42DF of approval of use of restricted representations by
Carl Zeiss Pty Ltd**

I, Leanne McCauley, Delegate of the Secretary to the Department of Health for the purposes of section 42DF of the *Therapeutic Goods Act 1989* (the Act), advise that following receipt of an application from Carl Zeiss Pty Ltd, the restricted representations described in paragraph (a) (i) – (iii) below for use in advertisements directed to consumers, for the product identified in paragraph (b) were approved on 13 December 2019 for use in advertisements directed to consumers, provided the conditions identified in paragraphs (c) and (d) are met:

(a) advertisements are directed to consumers aged 45 and over:

i. Zeiss intraocular lenses are used in cataract surgery to replace the natural lens of the eye (or words to that effect);

and representations to the effect of:

ii. providing a short, simple, accurate and balanced definition of cataracts together with the common symptoms of the condition; and

iii. providing a simple, accurate and balanced description of cataract surgery.

(b) 'Carl Zeiss Pty Ltd – lens, intraocular, posterior chamber' - ARTG No. 151348 (the Device)

(c) advertisements for the Device in which any or all of the approved representations are used must contain advisory statements, prominently displayed or communicated¹, to the effect that:

- extraction of cataracts and replacement with an intraocular lens will require a surgical procedure;
- any surgical procedure carries risks. Before proceeding, you should seek your eye care professional's advice; and
- the Device must be represented in accordance with the primary intended purpose; that is as replacement lens used in cataract surgery. References to

¹ As defined in the applicable version of the Therapeutic Goods Advertising Code, as amended from time to time.

achieving spectacle independence through correction of refractive error must be clearly presented as a **potential** secondary benefit.

(d) advertisements for the Device in which references are made to the common symptoms of cataracts must also include the following advisory statement, prominently displayed or communicated², to the effect that:

- these symptoms can also be a sign of other eye problems. If you have any of these symptoms, check with your eye care professional.

Dated this 13th day of December 2019

Signed electronically

Leanne McCauley

Delegate of the Secretary to the Department of Health
Advertising Education and Assurance Section
Regulatory Education and Compliance Branch

² As defined in the applicable version of the Therapeutic Goods Advertising Code, as amended from time to time.