



Australian Government

Department of Health, Disability and Ageing

Therapeutic Goods Administration

Advertising Approval: AMO Australia Pty Ltd – ELITA femtosecond laser system - Femtosecond ophthalmic Yb: Glass laser system (ARTG 409564)

Therapeutic Goods Act 1989

Approval under section 42DF for use of restricted representations by AMO Australia Pty Ltd

I, Rowena Love, as a delegate of the Secretary to the Department of Health, Disability and Ageing, on receipt of an application from AMO Australia Pty Ltd, have approved under section 42DF of the *Therapeutic Goods Act 1989*, restricted representations to the effect of that described in paragraph (A), for use in advertisements for the product identified in paragraph (B), when the statements to the effect of those identified in paragraph (C) are prominently displayed or communicated¹ in the advertisement in which the restricted representations are used, subject to the conditions identified in paragraph (D).

(A)

- Smooth Incision Lenticular Keratomileusis (SILK) is a laser eye surgery treatment that offers vision correction for people with myopia with and without astigmatism.*
 - *The SILK procedure is performed using ELITA femtosecond laser system / ELITA.

(B)

- ELITA femtosecond laser system - Femtosecond ophthalmic Yb: Glass laser system (ARTG 409564).

(C)

- SILK is a surgical treatment and as with any medical procedure, risks and potential complications may occur.
- Consult your eye doctor to see if laser vision correction with SILK is suitable for you.

(D)

- Advertisements in which the representations described in paragraph (A) used must comply with the Therapeutic Goods Advertising Code.

¹ ***prominently displayed or communicated***, in relation to a statement in an advertisement, means:

(a) either:

(i) for a visual statement—easily read from a reasonable viewing distance for the particular media type in the context in which the advertisement is intended to be viewed; or

(ii) for a spoken statement—able to be clearly heard and understood; and

(b) repeated as often as necessary to be noticed by a viewer or listener

Dated this 26th day of June 2025

Signed electronically

Rowena Love

Delegate of the Secretary to the Department of Health, Disability and Ageing

Education Policy and Guidance Section

Regulatory Compliance Branch