Australian Government

Department of Health and Aged Care

Therapeutic Goods Administration

Eyerising International Pty Ltd – Eyerising Myopia Management Device - Home-use myopia control red light device' (ARTG 412752)

Therapeutic Goods Act 1989

Approval under section 42DF for use of restricted representations by Eyerising International Pty Ltd

I, Michael Shum, as a delegate of the Secretary to the Department of Health and Aged Care, on receipt of an application from Eyerising International Pty Ltd, have approved under section 42DF of the *Therapeutic Goods Act 1989*, the restricted representations described in paragraph (**A**), for use in advertisements for the product identified in paragraph **(B)**, when the statements identified in paragraph **(C)** are prominently displayed or communicated[1] in the advertisement in which the restricted representations are used (including on the label and packaging of the goods), subject to the conditions identified in paragraph **(D)**.

(A)

- The Eyerising Myopia Management Device is a home-use medical device that can slow the progression of myopia in myopic children aged 3 to 16 years old.
- The Eyerising Myopia Management Device / repeated low-level red-light therapy can help slow myopia progression by slowing the elongation of the eye.
- Representations that refer to 'myopia' in the context of the product's trade name 'Eyerising Myopia Management Device' when such representations make no other reference to 'serious forms'[2] of diseases, conditions, ailment or defects.
- Myopia is a common eye condition where distant objects appear blurred.

(B)

- Eyerising Myopia Management Device - Home-use myopia control red light device' (ARTG 412752).

(C)

- The Eyerising Myopia Management Device is exclusively available through eye care professionals (e.g. optometrists, ophthalmologists) for home use.
- Outcomes may vary for each patient.

---

[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

[2] serious, in relation to a form of a disease, condition, ailment or defect, has the meaning given by section 28 of the currently in force Therapeutic Goods Advertising Code

(D)

- Advertisements in which any one of the Approved Representations is used must comply with the Therapeutic Goods Advertising Code (the Code).

Dated this 29th day of November 2024

Signed electronically

Michael Shum

Delegate of the Secretary to the Department of Health and Aged Care

Advertising and Compliance Education and Policy Section

Regulatory Compliance Branch