

Health Sciences Authority
11 Biopolis Way #11-01 Helios
Singapore 138667
Tel: 65 6866 3400 Fax: 65 6478 9076
Website: www.hsa.gov.sg



31/10/2017

Chye Mun Kain

MAXTER HEALTHCARE PTE. LTD.
1 COMMONWEALTH LANE,
ONE COMMONWEALTH, #07-01/02,
SINGAPORE 149544

Dear Sir/Mdm,

Please refer to your Pre-Market Application submitted on 24/7/2017.
Job Reference No.: MD17641646S
Device Name(s): <Please refer to attached Schedule>

The Health Sciences Authority has completed the review of this application, and we are pleased to inform you that the information provided has been adequate to demonstrate the quality, safety, and performance of the product for supply. The application is approved effective from the date of this letter and approved indication(s) can be found in the schedule attached.

The registration of this medical device shall not be construed as approval of the use(s) of this medical device. Use of this medical device may be subject to restrictions under the Private Hospitals and Medical Clinics Act, Medical Registration Act or any other applicable legislation (e.g. Radiation Protection Act).

Please contact CHANDRASEKARAN Jayashree, Regulatory Specialist, at Tel: 6866 3590
or E-mail: Jayashree_CHANDRASEKARAN@hsa.gov.sg should you need further clarification.

Yours sincerely,
Wong Woei Jiuang (Ms)

A handwritten signature in black ink, appearing to read 'Wong Woei Jiuang', with a horizontal line underneath.

Director, Medical Devices Branch
for Group Director
Health Products Regulation Group

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THE SCHEDULE

No.	Device Proprietary/Brand Name	Intended Use
1	Aveo 1-Day Aspheric Soft Contact Lens	Aveo™ (Omafilcon A) 1-Day Aspheric Soft Contact Lens is indicated for the optical correction of refractive ametropia in phakic persons with non-diseased eyes that are myopic or hypermetropic and exhibit astigmatism up to 0.75D.

END OF PRODUCT LIST