

CooperVision Contact Lens (M) Sdn Bhd 50-1-11 & 12 Level 1 Wisma UOA Damansara No 50 Jalan Dungun Damansara Heights 50490 Kuala Lumpur Main Line : 603 2080 8481 Fax: 603 2093 7533

Co. Reg. No.: 716244-U

## Letter of Explanation Biofinity (comfilcon A) contact lenses (3pk)

Dear Business Partners and Customers,

This letter is to explain the incorrect registration number inadvertently labelled on Biofinity contact lenses (3pk) distributed by CooperVision in Malaysia.

Biofinity is registered with Malaysia Medical Device Authority (MDA) since 11 January 2018, with Registration No.: **GB13979771318**. The registration remains valid until 10 January 2028. CooperVision became aware that some Biofinity contact lenses (3pk) cartons inadvertently displayed the incorrect MDA registration number, i.e. GB1397991318, due to incorrect information printed on the in-country label applied by the appointed 3<sup>rd</sup> Party Logistics service provider. CooperVision promptly rectified this error upon becoming aware of the same.

The in-country label with MDA registration number can be found at the back panel of the carton. The image below shows the Biofinity carton labelled with correct MDA Registration number GB13979771318 (blue arrow).

Contents: Biofinity® (comfilcon A 52%, H <sub>2</sub> O 48%)	
Tinted soft contact lenses in buffered saline	
Getönte weiche Kontaktlinsen in gepufferter Kochsalzlösung	
Lentes de contacto blandas tintadas en solución salina tamponada	
Centilles de contact souples avec teinte de manipulation, dans une solution saline tamponnée	
I Lenti a contatto morbide in soluzione salina tamponata leggermente colorate	
Getinte zachte contactlenzen in gebufferde zoutoplossing	
Lentes de contacto moles com coloração em solução salina tamponada	
Schrezett, May Local Authorized Representation: Schrezett, May Local Authorized Representation: Local	
	Contents: Biofinity® (comficen A 52%, H <sub>2</sub> O 48%) Contents: Biofinity® (comficent A 54%) Contents: Biofinity® (comficent A 54%) Contents: Biofinity® (comfittee B 56%) Contents: Biofinity® (comfitte

Aside from incorrect MDA Registration number, all product information, including but not limited to contents statement, lot number, expiry, and power parameters are correctly displayed. The affected products meet all safety and performance parameters. There is no, nor has there been any known reported cases of, health or safety risks associated with the use of Biofinity products that display the incorrect MDA registration number.

We apologize for any inconvenience to you or your customers. Should you wish to discuss this, please contact your account servicing representative.

Yours sincerely,

Dawn Lim General Manager, Southeast Asia