

Farmasia Sdn Bhd
March 31st, 2026

**MEDICAL DEVICE RECALL
BIO-AQUACEL EYE SAFE
MDA NO.: GB9985320-46507**

DEAR CUSTOMER,

Farmasia Sdn. Bhd. wishes to inform the public of a voluntary recall involving specific batches of BIO-AQUACEL Eye Safe with the previous packaging design.

Product Name : BIO-AQUACEL EYE SAFE

MDA NO. : GB9985320-46507

Intended Use : Intended for used as lubricant that gently soothes and moisturise eyes. This product is sterile and indicated for temporary relief of burning, irritation and discomfort due to dryness of eyes. Indication is to instil 1-2 drops into the affected eyes as needed, discard contents 4 weeks after opening.

Authorised Distributor : **TEGA KUANTUM SDN. BHD. (1078563-M)**
Block A-F-TG2 & A-F-TG3, FRIM-MTDC Technology Centre II,
Jalan Kapur, Forest Research Institution Malaysia,
52109, Kepong, Selangor.

Contact No.: +60 19-224 1336 (Person in Charge – Mr Lee)
Email: lee@bioaquacel.com

This recall applies ONLY to products manufactured and distributed by Farmasia Sdn. Bhd. from Year 2019 until August 2023, with the packaging as follows:



Any product bearing different or updated packaging design is **NOT** manufactured, supplied or distributed by Farmasia Sdn. Bhd.

Accordingly, such products do not fall within the scope of this recall and Farmasia Sdn. Bhd. makes no representation or warranty in respect of those products.

This recall is classified under *Class II – Medium Risk*. The reason for the voluntary recall is under the reason of **Contamination Problem – Code A18**. This problem associates with the presence of any unexpected foreign substance found in the device, which may affect performance or intended use of the device.

Consumers who experience any adverse effects after using the product are advised to seek medical advice immediately.

The registration of the affected product has been withdrawn from the Medical Device Authority (MDA). Therefore, the sale and distribution of the affected product is no longer authorised.

Note : This recall is made with the knowledge of the Medical Device Authority (MDA) AND conducted in accordance with the requirements of the Medical Device Authority (MDA), Malaysia

Thank you.