Alcon Laboratories (Malaysia) Sdn. Bhd.
Level 20-1, Tower B, Plaza 33, No. 1, Jalan Kemajuan,
Seksyen 13, 46200 Petaling Jaya,
Selangor, Malaysia.
Phone: +6(03)-27826888
Fax: +6(03)-27836950

May 5, 2025
MEDICAL DEVICE AUTHORITY
Ministry of Health Malaysia
Level 6, Prima 9, Prima Avenue II,
Block 3547, Persiaran APEC,
63000 Cyberjaya, Selangor,
MALAYSIA

Re: **Voluntary Medical Device Recall:** Constellation Pak®

Dear Medical Device Authority,

Alcon has initiated a Voluntary Medical Device Recall for specific lots of its Alcon Constellation Pak® due to the potential for the Tyvek® cover of some units within the affected lots to have been damaged during the manufacturing process. Due to the risk of Constellation Pak® sterility being compromised, Alcon is recalling potentially affected lots.

The use of non-sterile surgical products may increase the risk of post-operative infection, which may require additional medical and/or surgical intervention.

This event was identified internally by Alcon. As of April 29, 2025, Alcon has not received any reports of customer complaints or adverse events related to this issue.

This Voluntary Medical Device Recall affects customers globally. Alcon will contact affected customers by letter, email and/or direct phone call, as necessary, to provide information on actions required.

If you have any questions regarding this matter, please contact Mdm. Yap Ee Peng (Senior RA Manager) at ee_peng.yap@alcon.com ; +60124822620 or Mdm. Noor Hayati Abdul Wahab (GEM SEA QA Head) at noor_hayati.abdul_wahab@alcon.com

Alcon Laboratories (Malaysia) Sdn. Bhd.
Level 20-1, Tower B, Plaza 33, No. 1, Jalan Kemajuan,
Seksyen 13, 46200 Petaling Jaya,

Best Regards,

Yap, Ee Peng

Digitally signed by Yap, Ee Peng
DN: cn=Yap, Ee Peng, ou=PDF Internal Signing, o=Alcon Vision, LLC
Date: 2025.05.05 11:29:47 +08'00'

YAP EE PENG
Senior Regulatory Affairs Manager
Alcon Laboratories (Malaysia) Sdn. Bhd.