

Date of issuance: 9 March 2020

NOTIFICATION OF NON-COMPLIANCE

Notification no: NNC PP 001/2020

The following lot of Zenalb-20 50ml (20% Human Albumin) (MAL19991355AZ) produced by BIO PRODUCTS LABORATORY LIMITED, UNITED KINGDOM, whose numbers appear on the labels of the final containers, **DOES NOT MEET** the requirements as below:

- National requirement on Good Distribution Practice for Cold Chain
- National requirement on Lot Summary Protocol Evaluation
- National requirement on Physical Appearance Testing
- Requirements for the collection, processing and quality control of blood, blood components and plasma derivatives, WHO Technical Report Series, No.840, 1994, Annex 2

Submission of evidence of product destroy is compulsory before 9 July 2020

Product Registration Holder: GERMAX SDN BHD

Lot no: AHD19269

Expiry date: 30 June 2022

No. of container: 9,600

Signature:



Name of authorized person:

DATIN DR. FARIDAH ARYANI BINTI MD YUSOF
Director of National Pharmaceutical Regulatory Agency (NPRA)
Ministry of Health Malaysia