

Date of issuance: 19 August 2022

NOTIFICATION OF NON-COMPLIANCE

Notification no: NNC PP 001/2022

The following lot of I.V.-Globulin SN Inj. (50mg/mL) (MAL12085095AZ) produced by GREEN CROSS CORPORATION, SOUTH KOREA, 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

Product Registration Holder: **PROPHARM (M) SDN. BHD**

Lot no: 352B22001

Expiry date: 2 September 2024

No. of container: 140

Signature:

Name of authorized person:

NORHALIZA BINTI A HALIM
Senior Director of Pharmaceutical Services
Ministry of Health Malaysia