

Date of issuance: 14 June 2017

NOTIFICATION OF NON-COMPLIANCE

Notification no: NNC PP 001/2017

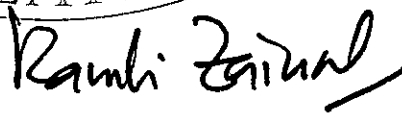
The following lot of Alphanine Injection SD 500 IU (MAL19950316AZ) produced by Grifols Biologicals Inc., USA, whose numbers appear on the labels of the final containers, **DOES NOT MEET** the requirements as below:

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

Lot No	Expiry date	No. of containers
A1XBB00032	* 30 November 2019	960

MALAYSIA

Signature:



Name of authorized person:

DR. RAMLI ZAINAL
Director of Pharmacy Regulatory
National Pharmaceutical Regulatory Division
Ministry of Health Malaysia

Date:

14 June 2017