

Date of issuance: 11 February 2019

NOTIFICATION OF NON-COMPLIANCE

Notification no: NNC PP 001/2019

The following lot of Human Albumin 20% Behring (Low Salt) Solution For Infusion (MAL20112131ARZ) produced by CSL Behring GmbH, Germany, 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
- 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
P100020752	30 April 2023	880

Signature:

Name of authorized person:

SITI AIDA BINTI ABDULLAH
Deputy Director for Pharmacy Regulatory
National Pharmaceutical Regulatory Agency (NPRA)
Ministry of Health Malaysia

Date:

11 February 2019