

Date of issuance: 27 September 2021

## NOTIFICATION OF NON-COMPLIANCE


### Notification no: NNC 004/2021

The following lot of COMIRNATY Concentrate for Dispersion for Injection (MAL21036039ASZ) produced by BioNTech Manufacturing GmbH, Mainz, GERMANY whose numbers appear on the labels of the final containers, **does not meet the requirements on product delivery and storage specification as approved by the Drug Control Authority and required by PIC/S Good Manufacturing Practice.**

Product Registration Holder: PFIZER (MALAYSIA) SDN. BHD.  
Lot no: FE8163  
Expiry date: 31 October 2021  
No. of doses: 5850 doses  
No. of doses per container: 6  
Receiving facility: Hospital Ampang

Signature:

Name of authorized person:

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