Date of issuance: 27 September 2021

NOTIFICATION OF NON-COMPLIANCE

Notification no: NNC 003/2021

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 Seberang Jaya

Signature:

Name of authorized person:

NORHALIZA BINTI A HALIM

Senior Director of Pharmaceutical Services

Ministry of Health Malaysia