Date of issuance: 31 Mac 2022

NOTIFICATION OF NON-COMPLIANCE

Notification no: NNC 002/2022

The following lot of COMIRNATY 10mcg Concentrate for Dispersion for Injection (MAL22016037AZ) 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:

FP8290

Expiry date:

31 Julai 2022

No. of doses:

BERTAMG,000 doses

No. of doses per container:

10

Receiving facility:

Klinik Kesihatan Bandar Kota Bharu

Signature:

Name of authorized person:

NORHALIZA PINTI A HALIM

Senior Director of Pharmaceutical Services

Ministry of Health Malaysia