Date of issuance:

23 November 2021

NOTIFICATION OF NON-COMPLIANCE

Notification no: NNC 008/2021

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:

BERSEKUTU

PFIZER (MALAYSIA) SDN. BHD.

Lot no:

FG6272

Expiry date:

31 March 2022

No. of doses:

5,850 doses

No. of doses per container BERTAME OF MUTUSTA

Receiving facility:

Hospital Queen Elizabeth

Signature:

Name of authorized person:

NORHALIZA/BINTIA HALIM

Senior Director of Pharmaceutical Services

Ministry of Health Malaysia