

SCHOTT KAISHA PRIVATE LIMITED  
Admin. Office :  
1st Floor, Mittal Chambers,  
228, Nariman Point,  
Mumbai 400 021, INDIA.  
Phone +91 (22) 61 51 57 00 - 03  
Fax +91 (22) 22 88 64 42

## LETTER OF AUTHORIZATION (LOA)

Date: 06 May 2021

Subject: Letter of Authorization for: **Neutral Glass Tubings USP Type I**, Reference Schott Kaisha Drug Master File No. 031786 Type – III : “Glass Ampoules, Glass Vials, Glass Cartridges and Glass Syringes”

DMF #: 031786

Holder: *SCHOTT KAISHA PVT. LTD.*

Dear DMF Staff:

*SCHOTT KAISHA PVT. LTD.*, hereby authorizes **Pfizer Inc., as US Agent for BioNTech RNA Pharmaceuticals GmbH, 500 Arcola Road, Collegeville, PA 19436**, to incorporate any reference information regarding **2ml Vial Clear -13mm-European Blow Back** cited in DMF 031786 into **BLA for Intramuscular, BNT162b2 vaccine, Concentration 0.5 mg/ml** filed by **Pfizer Inc.** We also authorize the FDA to review the afore mentioned specific information in DMF 031786 when considering any **BLA** for the above product filed by **Pfizer Inc.**

We request that all information in this file be treated as confidential to the extent possible in accordance with 21 CFR 314.430 and 21 CFR 20.61 and that no information from this file be provided to any unauthorized persons without our written consent. This authority is granted for as long as this DMF is active, or until the FDA is notified to rescind the authority.

*SCHOTT KAISHA PVT. LTD.*, states that DMF 031786 is current and, will comply with the statements made within it and will notify FDA through an amendment / update to DMF 031786 of any addition, change, or deletion of information in the DMF.

*SCHOTT KAISHA PVT. LTD.*, will also notify in writing to **Pfizer Inc.**, any addition, change, or deletion of information pertaining to the product cited in LOA that has been made to the DMF.

Sincerely,

*NP* 06 MAY 2021

Mr. Debashish Panda  
(Authorised Signatory)

090177e196fde963Approved On: 10-May-2021 08:45 (GMT)