

## Medical Systems

Gerresheimer Buende GmbH · Postfach 14 49 · 32255 Buende · Germany

Food and Drug Administration  
Center for Drug Evaluation and Research  
Central Document Room  
Drug Master File Staff  
5901-B Ammendale Rd.  
Beltsville, MD 20705-1266

USA

Gerresheimer Buende GmbH  
Erich-Martens-Strasse 26 - 32  
32257 Buende  
Germany

Chairman of the Supervisory Board:  
Dietmar Siemssen

Management Board:  
Manfred Baumann, Oliver Burgel

Registered Seat: Buende  
Local Court Bad Oeynhausen HRB 7866

Chassandra Koch  
Regulatory Affairs  
Telephone +49 5223 164-337  
Telefax +49 5223 164-211  
E-Mail [chassandra.koch@gerresheimer.com](mailto:chassandra.koch@gerresheimer.com)  
Internet [www.gerresheimer.com](http://www.gerresheimer.com)

September 14, 2020

## Letter of Authorization

Dear Sir or Madam,

This letter is to authorize your division to refer to the following Drug Master File in connection with any NDA, ANDA, INDA, PMA, PAS or comparable activities filed by Pfizer Inc. as US Agent for BioNTech RNA Pharmaceuticals GmbH, 500 Arcola Road, Collegeville, PA 19436

- |                        |   |   |
|------------------------|---|---|
| 1. DMF holder          | : | Gerresheimer Bünde GmbH, Germany  |
| 2. DMF number          | : | DMF 15209   |
| 3. Authorized person   | : | Chassandra Koch<br>Manager Regulatory Affairs   |
| 4. Title of submission | : | Type III; Containers made from tubular glass as ampoules, bulk syringes, cartridges and vials up to 100ml to be used as primary packaging containers for pharmaceutical and medicinal products  |
| 5. Submission date     | : | <i>original:</i> December 21, 2000<br><i>revision:</i> December 05, 2011  |
| 6. Submitted by        | : | <i>original:</i> Bündler Glas GmbH, Germany<br><i>revision:</i> Gerresheimer Bünde GmbH, Germany  |
| 7. Stmt. of commitment | : | Wishes to state that the Gerresheimer Bünde DMF 15209 is correct and complete and that no changes in the formulation and specification will be made without notifying Pfizer Inc. as US Agent for BioNTech RNA Pharmaceuticals GmbH, 500 Arcola Road, Collegeville, PA 19436. |

It is understood that the formulation itself will be maintained confidential.

Yours sincerely,

Gerresheimer Buende GmbH



Chassandra Koch  
Manager Regulatory Affairs