

MANUFACTURER'S AUTHORISATION^{1, 2}

1. Authorisation Number DE_HE_01_MIA_2021_0002
2. Name of authorisation holder BioNTech Manufacturing Marburg GmbH
3. Address(es) of manufacturing site(s) BioNTech Manufacturing Marburg GmbH, Emil-von-Behring-Strasse 76, Gebaeude H 28 und H 30, Marburg, Hessen, 35041, Germany
4. Legally registered address of authorisation holder Emil-von-Behring-Strasse 76, Marburg, Hessen, 35041, Germany
5. Scope of authorisation and dosage forms² ANNEX 1 and/ or ANNEX 2
6. Legal Basis of authorisation Art. 40 of Directive 2001/83/EC
7. Name of responsible officer of the competent authority of the member state granting the manufacturing authorisation confidential
8. Signature
9. Date 2021-01-28
10. Annexes attached Annex 1 and/or Annex 2
Optional Annexes as required:
Annex 3 (Addresses of Contract Manufacturing Site(s))
Annex 4 (Addresses of Contract laboratories)
Annex 5 (Name of Qualified Person)
Annex 6 (Name of responsible persons)
Annex 7 (Date of inspection on which authorisation granted, scope of last inspection)
Annex 8 (Manufactured/ imported products authorised)³

¹ The authorisation referred to in paragraph 40(1) of Directive 2001/83/EC and 44(1) of Directive 2001/82/EC, as amended, shall also be required for imports coming from third countries into a Member State.

² Guidance on the interpretation of this template can be found in the Help menu of EudraGMDP database.

³ The Competent Authority is responsible for appropriate linking of the authorisation with the manufacturer's application (Art. 42(3) of Directive 2001/83/EC and Art. 46(3) of Directive 2001/82/EC as amended).

SCOPE OF AUTHORISATION

ANNEX 1

Name and address of the site : BioNTech Manufacturing Marburg GmbH,
Emil-von-Behring-Strasse 76, Gebaeude H 28 und H 30,
Marburg, Hessen, 35041, Germany

Human Medicinal Products

Authorised Operations MANUFACTURING OPERATIONS (according to part 1)
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Part 1 - MANUFACTURING OPERATIONS	
1.3	Biological medicinal products (list of product types)
	<i>1.3.1 Biological medicinal products (list of product types)</i> 1.3.1.2 Immunological products
1.4	Other products or manufacturing activity
	<i>1.4.1 Manufacture of</i> 1.4.1.3 Other: API of biotechnological origin: - mRNA-based API BNT162b2 Starting material linerized plasmid-DNA - in vitro transcribed mRNA solution BNT162b2 Starting material linerized plasmid-DNA(en)
1.6	Quality control testing
	<i>1.6.2 Microbiological: non-sterility</i> <i>1.6.3 Chemical/Physical</i> <i>1.6.4 Biological</i>

Any restrictions or clarifying remarks related to the scope of these Manufacturing operations (for Public users)

Partial testing in contract laboratories according to sect 14 para 4 German Drug law (see annex 4).
Holding in external warehouses, see separate document. contractual partner for storage of
documents: Iron Mountain Deutschland GmbH Am Magnapark / Unit 2 35510 Butzbach Germany