



BE IT KNOWN that I, Sunita Kumeri of, 268 Bath Road, Slough, Berkshire United Kingdom a duly authorised Notary Public

CERTIFY that

1. The signature set and subscribed to the certificate at the foot of the first page of the copy document annexed hereto is genuine having been subscribed thereto by Zoe Bruce whose identity I the Notary attest and who is duly authorised by Pfizer Limited ("the Company") to represent them in this matter, and Zoe Bruce has thereby certified on behalf of the company that the Certificate of GMP Compliance of a Manufacturer for Pfizer Manufacturing Belgium NV annexed hereto is a true copy of the original document.

SIGNED and sealed at 268 Bath Road, Slough, Berkshire aforesaid 30th November 2020

Sunita Kumeri
Notary Public
England and Wales

Protocol No. 40/20





APOSTILLE

(Convention de La Haye du 5 octobre 1961)

1. **Country:** United Kingdom of Great Britain and Northern Ireland
Pays / Pais:

This public document

Le présent acte public / El presente documento público

2. **Has been signed by**
a été signé par Sunita Kumeri
ha sido firmado por

3. **Acting in the capacity of**
agissant en qualité de Notary Public
quien actúa en calidad de

4. **Bears the seal / stamp of**
est revêtu du sceau / timbre de The Said Notary Public
y está revestido del sello / timbre de

Certified

Attesté / Certificado

5. **at** London
à / en
6. **the** 01 December 2020
le / el día

7. **by** Her Majesty's Principal Secretary of State for
par / por Foreign, Commonwealth and Development Affairs

8. **Number** APO-2148005
sous no / bajo el numero

9. **Seal / stamp**
Sceau / timbre
Sello / timbre



10. **Signature** A. Monk
Signature
Firma

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Federal Agency for Medicines and Health Products

CERTIFICATE NUMBER: **BE/GMP/2020/034**

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER

Part 1

Issued following an inspection in accordance with :
Art. 111(5) of Directive 2001/83/EC as amended

The competent authority of Belgium confirms the following:

The manufacturer: **Pfizer Manufacturing Belgium NV**

Site address: **Rijksweg 12, Puurs, 2870, Belgium**

Has been inspected under the national inspection programme in connection with manufacturing authorisation no. **277 H** in accordance with Art. 40 of Directive 2001/83/EC transposed in the following national legislation:

Article 12 bis, § 1 of the Law of 25th March 1964 related to the Medicinal Products

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on **2020-07-15**, it is considered that it complies with :

- The principles and guidelines of Good Manufacturing Practice laid down in Directive 2003/94/EC³

This certificate reflects the status of the manufacturing site at the time of the inspection noted above and should not be relied upon to reflect the compliance status if more than three years have elapsed since the date of that inspection. However, this period of validity may be reduced or extended using regulatory risk management principles by an entry in the Restrictions or Clarifying remarks field. This certificate is valid only when presented with all pages and both Parts 1 and 2. The authenticity of this certificate may be verified in EudraGMDP. If it does not appear, please contact the issuing authority.

¹ The certificate referred to in paragraph 111(5) of Directive 2001/83/EC and 80(5) of Directive 2001/82/EC, 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 These requirements fulfil the GMP recommendations of WHO.

I, Zoe Bruce, on behalf of Pfizer
certify this document
to be a true copy
of the original

Part 2

Human Medicinal Products	
1 MANUFACTURING OPERATIONS	
1.1	Sterile products
	<i>1.1.1 Aseptically prepared (processing operations for the following dosage forms)</i> 1.1.1.4 Small volume liquids
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

Clarifying remarks (for public users)

Inspected area/activities: Small Scale Fill & Finish (S2F2), filling of immunological products only

2020-09-11

Name and signature of the authorised person of the
Competent Authority of Belgium

Confidential

Federal Agency for Medicines and Health Products

Tel: **Confidential**

Fax: **Confidential**