



BE IT KNOWN that I Laura Anne Pawley, Mezzanine Floor, Epsom Square, Epsom, Surrey, KT19 8AG, a duly authorised Notary Public, duly admitted, sworn and practice throughout England and Wales.

That on the 25<sup>th</sup> November 2024, I caused an inspection to be made at the Federal Agency for Medicines and Health Products (FAMHP) and based on such I hereby certify the following.

**THAT** the annexed Certificate of GMP Compliance of a Manufacturer issued to Pfizer Manufacturing Belgium for use in Chile is a true and correct original electronic document issued by the FAMHP.

Protocol No: 2024-7047

**SIGNED** and sealed at Mezzanine Floor, Epsom Square, Epsom, Surrey, KT19 8AG on the 25<sup>th</sup> November 2024.

Laura Anne Pawley  
Notary Public



## APOSTILLE

(Convention de La Haye du 5 octobre 1961)

<b>1. Country:</b> Pays / País:	United Kingdom of Great Britain and Northern Ireland		
<b>This public document</b> Le présent acte public / El presente documento público			
<b>2. Has been signed by</b> a été signé par ha sido firmado por	Laura Anne Pawley		
<b>3. Acting in the capacity of</b> agissant en qualité de quien actúa en calidad de	Notary Public		
<b>4. Bears the seal / stamp of</b> est revêtu du sceau / timbre de y está revestido del sello / timbre de	The Said Notary Public		
<b>Certified</b> Attesté / Certificado			
<b>5. at</b> á / en	London	<b>6. the</b> le / el día	27 November 2024
<b>7. by</b> par / por	His Majesty's Principal Secretary of State for Foreign, Commonwealth and Development Affairs		
<b>8. Number</b> sous no / bajo el numero	APO-KLKF-FUTZ-6EPC-LNHK		
<b>9. Seal / stamp</b> Sceau / timbre Sello / timbre			
<b>10. Signature</b> Signature Firma	A. Kurt 		

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## Federal Agency For Medicines And Health Products

CERTIFICATE NUMBER: **BE/GMP/2024/038**

# CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER<sup>1,2</sup>

### 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**

Manufacturer's alternative name: **Pfizer Manufacturing Belgium N.V.**

Site address: **Rijksweg 12, Puurs-Sint-Amands, 2870, Belgium, GPS: 51.065949, 4.314205**

OMS Organisation Id. / OMS Location Id.: **ORG-100005177 / LOC-100002937**

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 for Human Use**

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on **2024-03-21**, it is considered that it complies with:

- The principles and guidelines of Good Manufacturing Practice laid down in Directive (EU) 2017/1572 and/or Commission Delegated Regulation (EU) 2017/1569, as reflected by the product categories stated in Part 2.<sup>3</sup>

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. Updates to restrictions or clarifying remarks can be identified through the EudraGMDP website (<http://eudragmdp.ema.europa.eu/>). 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.

<sup>1</sup>The certificate referred to in paragraph Art. 111(5) of Directive 2001/83/EC is also applicable to importers.

<sup>2</sup>Guidance on the interpretation of this template can be found in the Interpretation of the Union format for GMP certificate.

<sup>3</sup>These requirements fulfil the GMP recommendations of WHO.

Part 2

Human Medicinal Products

**1 MANUFACTURING OPERATIONS**

<b>1.1</b>	<b>Sterile products</b>
	<p><i>1.1.1 Aseptically prepared (processing operations for the following dosage forms)</i></p> <p>1.1.1.2 Lyophilisates Special Requirements 7 Other: Highly potent products / certain hormones(en)</p> <p>1.1.1.3 Semi-solids Special Requirements 7 Other: Highly potent products / certain hormones(en)</p> <p>1.1.1.4 Small volume liquids Special Requirements 7 Other: Highly potent products / certain hormones(en)</p>
	<p><i>1.1.2 Terminally Sterilised (processing operations for the following dosage forms)</i></p> <p>1.1.2.3 Small volume liquids</p>
	<p><i>1.1.3 Batch certification</i></p>
<b>1.3</b>	<b>Biological medicinal products (list of product types)</b>
	<p><i>1.3.1 Biological medicinal products (list of product types)</i></p> <p>1.3.1.2 Immunological products Special Requirements 7 Other: formulation and filling only(en)</p> <p>1.3.1.5 Biotechnology products Special Requirements 7 Other: formulation and filling only(en)</p> <p>1.3.1.6 Human or animal extracted products Special Requirements 7 Other: formulation and filling only and special requirement low molecular weight heparine(en)</p>
	<p><i>1.3.2 Batch Certification (list of product types)</i></p> <p>1.3.2.2 Immunological products</p> <p>1.3.2.5 Biotechnology products</p> <p>1.3.2.6 Human or animal extracted products</p>
<b>1.5</b>	<b>Packaging</b>
	<p><i>1.5.2 Secondary packaging</i></p>

<b>1.6</b>	<b>Quality control testing</b>
	1.6.1 <i>Microbiological: sterility</i>
	1.6.2 <i>Microbiological: non-sterility</i>
	1.6.3 <i>Chemical/Physical</i>
	1.6.4 <i>Biological</i>

<b>2 IMPORTATION OF MEDICINAL PRODUCTS</b>	
<b>2.1</b>	<b>Quality control testing of imported medicinal products</b>
	2.1.1 <i>Microbiological: sterility</i>
	2.1.2 <i>Microbiological: non-sterility</i>
	2.1.3 <i>Chemical/Physical</i>
	2.1.4 <i>Biological</i>

2024-07-10

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


  
Séverine BRASSEUR  
 File Manager,  
 129 Inspection FAMEP

**Ethel Mertens**  
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