APOSTILLE

(Convention de La Haye du 5 octobre 1961)

1. Land/Pays/Land: ***BELGIË - BELGIQUE - BELGIEN***

2. Deze openbare akte is ondertekend door :
Le présent acte a été signé par :
Diese öffentliche Urkunde ist unterschrieben von : ***Brasseur Séverine***

3. Handelend in hoedanigheid van :
Agissant en qualité de :
In seiner/ihrer Eigenschaft als : ***Attaché/Attaché/Attaché***

4. Is voorzien van het zegel van :
Est revêtu du sceau de :
Sie ist versehen mit dem Siegel des/der : ***FAGG/AFMPS/FAGG/FAMPS***

Voor echt verklaard / Attesté / Bestätigt

5. ***Te Brussel/A Bruxelles/In Brüssel*** 6. Op/Le/Am : ***01/04/2020***

7. Door FOD Buitenlandse Zaken, Buitenlandse Handel en Ontwikkelingssamenwerking
Par le SPF Affaires étrangères, Commerce extérieur et Coopération au Développement
Durch FÖD Auswärtige Angelegenheiten, Außenhandel und Entwicklungszusammenarbeit

8. Onder Nr./Sous le n°/Unter Nr. : ***200477598297***

9. Stempel/Sceau/Stempel:

10. Ondertekening/Signature/Unterschrift:

Digitally signed by
FPS Foreign Affairs
Belgium

Prijs/Prix/Preis: ***20*** EUR

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EUROSTATION II
Place Victor Hortaplein 40/40
1060 BRUSSELS (BELGIUM)
http://www.fagg-afmps.be

Federal Agency for Medicines and Health Products

CERTIFICATE NUMBER: ***BE/GMP/2017/001***

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER [1, 2]

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 ***2017-01-26*** , it is considered that it complies with :

- The principles and guidelines of Good Manufacturing Practice laid down in Directive 2003/94/EC [3]

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.*

Part 2

Human Medicinal Products

1 MANUFACTURING OPERATIONS	
1.1	**Sterile products**
	1.1.1 Aseptically prepared (processing operations for the following dosage forms) 1.1.1.2 Lyophilisates Special Requirements 7 Other: hormones/prostaglandins(en) 1.1.1.3 Semi-solids Special Requirements 7 Other: prostaglandins(en) 1.1.1.4 Small volume liquids Special Requirements 7 Other: hormones/prostaglandins(en)
	1.1.2 Terminally Sterilised (processing operations for the following dosage forms) 1.1.2.3 Small volume liquids
	1.1.3 Batch certification
1.3	**Biological medicinal products (list of product types)**
	1.3.1 Biological medicinal products (list of product types) 1.3.1.2 Immunological products 1.3.1.5 Biotechnology products 1.3.1.6 Human or animal extracted products 1.3.1.8 Other
	1.3.2 Batch Certification (list of product types) 1.3.2.2 Immunological products 1.3.2.5 Biotechnology products 1.3.2.6 Human or animal extracted products

2 IMPORTATION OF MEDICINAL PRODUCTS	
2.2	**Batch certification of imported medicinal products**
	2.2.2 Non-sterile products

Clarifying remarks (for public users)

For Aseptic North area: the duration of validity of this GMP certificate has been extended with 1 year.
For all other area's: the duration of validity of this GMP certificate has been extended with 3 months.

2020-02-04

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

Severine BRASSEUR
pde Manager
DG Inspection-FAMHP

Confidential
Federal Agency for Medicines and Health Products
Tel: ***Confidential***
Fax: ***Confidential***