

APOSTILLE

(Convention de La Haye du 5 octobre 1961)

1. Country: Sweden

This public document

2. has been signed by Adrienne Bonde

3. acting in the capacity of Deputy Notary Public

4. bears the seal/stamp of Notary Public in
Stockholm

Certified

5. at Stockholm

6. The 2018-07-26

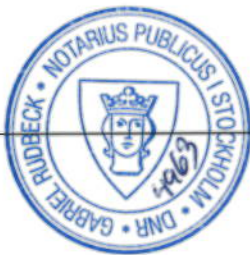
7. by Gabriel Rudbeck

Notary Public

8. N^o 6057

9. Seal/stamp:

10. Signature:



A handwritten signature in blue ink, consisting of several loops and a long horizontal stroke at the end.

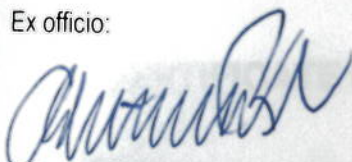
NOTARY PUBLIC

I, the undersigned Adrienne Bonde, Deputy Notary Public of the City of Stockholm, Sweden, hereby certify,

that this document is a true and correct copy of the document produced to me.

Stockholm, Sweden 2018-07-26

Ex officio:



Adrienne Bonde

Sveavägen 24-26, P O Box 3098, S-103 61 Stockholm, +46 (0) 8 20 59 90



Medical Products AgencyCERTIFICATE NUMBER: **6.2.1-2017-061518****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 Sweden confirms the following:

The manufacturer: **Pfizer Health AB**

Site address: **Mariefredsvägen 37, Strängnäs, 645 41, Sweden**

Has been inspected under the national inspection programme in connection with manufacturing authorisation no. **6.2.1-2017-061518** in accordance with Art. 40 of Directive 2001/83/EC .

Is an active substance manufacturer that has been inspected in accordance with Art. 111(1) of Directive 2001/83/EC .

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on **2017-10-13** , it is considered that it complies with :

- The principles and guidelines of Good Manufacturing Practice laid down in Directive 2003/94/EC³
- The principles of GMP for active substances³ referred to in Article 47 of Directive 2001/83/EC .

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

1.3 Biological medicinal products (list of product types)

1.3.1 Biological medicinal products (list of product types)

1.3.1.5 Biotechnology products

1.3.1.8 Other: Cellbank(en)

1.6 Quality control testing

1.6.2 Microbiological: non-sterility

1.6.3 Chemical/Physical

1.6.4 Biological

Clarifying remarks (for public users)

1.3.1.5 Manufacturing of biotech drug substances and intermediates based on recombinant bacterial products or polysaccharide. (Tillverkning av bioteknologiska aktiva substanser och intermediat baserade på rekombinanta bakteriella produkter eller polysackarider.) 1.3.1.8 Manufacturing and storage of cellbank. (Tillverkning och förvaring av cellbank.)

2018-06-21

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

Bengt Berglund

Mr. Bengt Berglund
Medical Products Agency

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Fax: +46 18 548566

