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/2018/132***

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: ***Alcon-Couvreur NV***
Site address: ***Rijksweg 14, Puurs, 2870, Belgium***

Has been inspected under the national inspection programme in connection with manufacturing authorisation no. ***176 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 ***2018-11-09*** , 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.*

Chile 162283

Part 2

Human Medicinal Products	

1 MANUFACTURING OPERATIONS	
1.1	**Sterile products**
	1.1.1 Aseptically prepared (processing operations for the following dosage forms) 1.1.1.3 Semi-solids 1.1.1.4 Small volume liquids Special Requirements 7 Other: prostaglandin(en)
	1.1.3 Batch certification
1.3	**Biological medicinal products (list of product types)**
	1.3.2 Batch Certification (list of product types) 1.3.2.5 Biotechnology products
1.5	**Packaging**
	1.5.2 Secondary packing
1.6	**Quality control testing**
	1.6.1 Microbiological: sterility *1.6.2 Microbiological: non-sterility* *1.6.3 Chemical/Physical* *1.6.4 Biological*

2 IMPORTATION OF MEDICINAL PRODUCTS	
2.1	**Quality control testing of imported medicinal products**
	2.1.1 Microbiological: sterility *2.1.2 Microbiological: non-sterility* *2.1.3 Chemical/Physical* *2.1.4 Biological*
2.2	**Batch certification of imported medicinal products**
	2.2.1 Sterile products 2.2.1.1 Aseptically prepared 2.2.1.2 Terminally sterilised
2.3	**Other importation activities**
	2.3.1 Site of physical importation
	2.3.2 Importation of intermediate which undergoes further processing

The State of Texas

Secretary of State

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Certificate Validation available at www.sos.state.tx.us

APOSTILLE

(Convention de La Haye du 5 Octobre 1961)

1. Country	United States of America
This public document	
2. has been signed by	CAROLE YOUMBI YAMDJEU
3. acting in the capacity of	Notary Public, State of Texas
4. and bears the seal/stamp of	CAROLE YOUMBI YAMDJEU, Notary Public, State of Texas, Commission Expires: 05-21-22

CERTIFIED

5. at Austin, Texas
6. on April 3, 2019
7. by the Secretary of State of Texas
8. Certificate No. 11704627
9. Seal
10. Signature:

David Whitley
Secretary of State

GF/rm

Clarifying remarks (for public users)

2019-02-12

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

Mr. Xavier De Cuyper
Federal Agency for Medicines and Health Products
Tel: *+32 2 5284000*
Fax: *+32 2 5284001*

State of Texas
County of Tarrant

On this 29th **day of** March **,** 2019.
I certify that the preceding document, and the duplicate retained by me as a notarial record, are true, exact, complete and unaltered photocopies made by me of

Certificate BE/GMP/2018/132.

presented to me by the document's custodian, Alcon Laboratories, and that, to the best of my knowledge, the photocopied document is neither a public record nor a publicly recordable document, certified copies of which are available from an official source other than a notary.

Carole Youmbi

CAROLE YOUMBI YAMDJEU
NOTARY PUBLIC
STATE OF TEXAS
NOTARY ID 131606[illegible]
EXPIRES 05-21-2022