Health Care Inspectorate - Pharmaceutical Affairs and Medical Technology

CERTIFICATE NUMBER: ***NL/H15/1003247***

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 Netherlands confirms the following:
The manufacturer: ***Svizera Europe B.V.***
Site address: ***Antennestraat 84, ALMERE, 1322AS, Netherlands***

Has been inspected under the national inspection programme in connection with manufacturing authorisation no. ***4909 F*** in accordance with Art. 40 of Directive 2001/83/EC transposed in the following national legislation:
Art. 100 of the Medicines Act

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on ***2014-11-04*** , 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 EudraGMP. If it does not appear, please contact the issuing authority.

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[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

2 IMPORTATION OF MEDICINAL PRODUCTS	
2.2	**Batch certification of imported medicinal products**
	2.2.2 Non-sterile products
2.3	**Other importation activities**
	2.2.1 Site of physical importation

2015-04-08

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

Inspectie voor de Gezondheidszorg
Rijksoverheid
Ministerie van Volksgezondheid, Welzijn en Sport

Ms. Annelies Sprenkels
Health Care Inspectorate - Pharmaceutical Affairs and Medical Technology
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Health Care Inspectorate - Pharmaceutical Affairs and Medical Technology

Certificate No: NL/G 15/1003247

CERTIFICATE OF GDP COMPLIANCE OF A WHOLESALE DISTRIBUTOR

Issued following an inspection in accordance with Art. 111 of Directive 2001/83/EC

The competent authority of Netherlands confirms the following:

The wholesale distributor: Svizera Europe B.V.

Site address: Antennestraat 84, ALMERE, 1322AS, Netherlands

Has been inspected under the national inspection programme in connection with authorisation number 4825 G in accordance with Art. 77 (1) of Directive 2001/83/ EC transposed in the following national legislation: Art. 100 of the Medicines Act

From the knowledge gained during inspection of this wholesale distributor, the latest of which was conducted on 2014-11-04, it is considered that it complies with the Good Distribution Practice requirements laid down in Article 84 of Directive 2001/83/EC.

This certificate reflects the status of the premises at the time of the inspection noted above and should not be relied upon to reflect the compliance status if more than five years have elapsed since the date of that inspection. However this period of validity may be reduced 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.

The authenticity of this certificate may be verified in the Union database. If it does not appear please contact the issuing authority.

2015-04-14

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

Inspectie voor de Gezondheidszorg
Ministerie van Volksgezondheid, Welzijn en Sport
Rijksoverheid

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Details of the authorisation can be found in the Union Database.