

Registration number 4825 G

Our ref.
Farmatec-BMC/JZ-10428

Our reference
Farmatec-BMC/JZ-10428

The Hague
16 July 2010

WHOLESALE R'S AUTHORIZATION

The Minister for Health, Welfare and Sport,

Considering the application by Svizera Europe B.V. in Almere, the Netherlands (dossier number 11058099, stated on the excerpt from the Trade Register of the Chamber of Commerce for Gooi-, Eem- and Flevoland), 2 June 2010, received on 3 February 2010;

Considering article 18, first paragraph, of the Dutch Medicines Act [*Geneesmiddelenwet*];

DECIDES:

1. To grant Svizera Europe B.V., Antennestraat 43, ALMERE, an authorisation to deliver pharmaceutical products that have been purchased in states that are a party to the Agreement regarding the European Economic Area (EEA; the EU Member states, plus Iceland, Liechtenstein and Norway).
2. The products may only be stocked for delivery at the location on Antennestraat 43 in Almere.
3. For purposes of this authorisation the following person may act as responsible person:
Mr J. Heymenberg.

The Minister for Health, Welfare and Sport,
On whose behalf,
Unit Farmatec-BMC
was signed

[signature]

Ms A.J. Hennis
Acting Unit Head





> Return address PO Box 16114 2500 BC The Hague, the Netherlands

MANUFACTURERS AUTHORISATION OF SVIZERA EUROPE B.V., ALMERE, THE NETHERLANDS, GRANTED ON 16 JULY 2010	
1. AUTHORISATION NUMBER	
4909 F	
2. NAME OF AUTHORISATION HOLDER	
Svizera Europe B.V., in ALMERE	
3. SITE(S)	
ALMERE	Antennestraat 43, 1322 AH ALMERE
4. ADDRESS OF AUTHORISATION HOLDER	
Antennestraat 43, 1322 AH ALMERE	
5. SCOPE OF AUTHORISATION	
Importation of medicinal products	
6. LEGAL BASIS OF AUTHORISATION	
Article 18, subsection 1, of the Dutch Medicines Act [<i>Geneesmiddelenwet</i>]	
7. ANNEXES TO THE AUTHORISATION	
Annex 1, part 1:	Manufacturing of medicinal products
Annex 1, part 2:	Importation of medicinal products
Annex 2, part 1:	Manufacturing of investigational medicinal products
Annex 2, part 2:	Importation of investigational medicinal products
Annex 3:	Contract laboratories
Annex 4:	QPs
8. SIGNATURE	
The Minister for Health, Welfare and Sport, On his behalf Unit Farmatec-BMC was signed [signature] Ms A.J. Hennis Acting Unit Head	





SCOPE OF AUTHORISATION

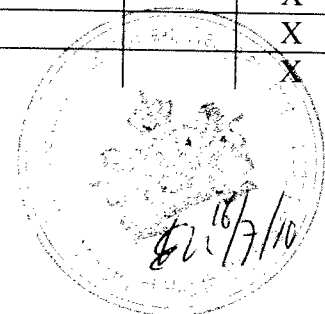
Name and address of the site: ALMERE, at Antennestraat 43, 1322 AH ALMERE

X	HUMAN MEDICINAL PRODUCTS
	INVESTIGATIONAL MEDICINAL PRODUCTS

AUTHORISED OPERATIONS	
	MANUFACTURING OPERATIONS (ACCORDING TO PART 1)
X	IMPORTATION OF MEDICINAL PRODUCTS (ACCORDING TO PART 2)

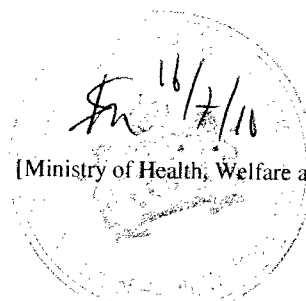
PART 1 – MANUFACTURING OPERATIONS	
<p>- authorised manufacturing operations include total and partial manufacturing (including various processes of dividing up, packaging or presentation), batch release and certification, importation, storage and distribution of specified dosage forms unless informed to the contrary;</p> <p>- quality control testing and/or release and batch certification activities without manufacturing operations should be specified under the relevant items;</p> <p>- if the company is engaged in the manufacture of products with special requirements, e.g. radiopharmaceuticals or products containing penicillin, sulphonamides, cytotoxics, cephalosporins, substances with hormonal activity or other potentially hazardous active ingredients, this should be stated under the relevant product type and dosage form.</p>	

		Yes	No
1.1	STERILE PRODUCTS		X
	<i>1.1.1 Aseptically prepared (list of dosage forms)</i>		X
	1.1.1.1 Large volume liquids		X
	1.1.1.2 Lyophilisates		X
	1.1.1.3 Semi-solids		X
	1.1.1.4 Small volume liquids		X
	1.1.1.5 Solids and implants		X
	1.1.1.6 Other aseptically prepared products		X
	<i>1.1.2 Terminally sterilised (list of dosage forms)</i>		X
	1.1.2.1 Large volume liquids		X
	1.1.2.2 Semi-solids		X
	1.1.2.3 Small volume liquids		X
	1.1.2.4 Solids and implants		X
	1.1.2.5 Other terminally sterilised products		X
	<i>1.1.3 Batch certification only (in case you would have dosage forms in this product group contract manufactured)</i>		X
1.2	NON-STERILE PRODUCTS		X
	<i>1.2.1 Non-sterile products (list of dosage forms)</i>		X
	1.2.1.1 Capsules, hard shell		X



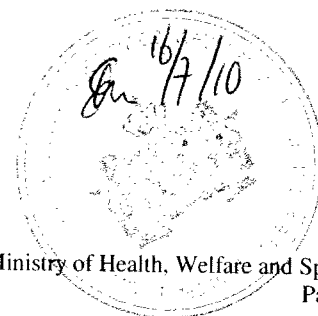


	1.2.1.2 Capsules, soft shell		X
	1.2.1.3 Chewing gums		X
	1.2.1.4 Impregnated matrices		X
	1.2.1.5 Liquids for external use		X
	1.2.1.6 Liquids for internal use		X
	1.2.1.7 Medicinal gases		X
	1.2.1.8 Other solid dosage forms		X
	1.2.1.9 Pressurised preparations		X
	1.2.1.10 Radionuclide generators		X
	1.2.1.11 Semi-solids		X
	1.2.1.12 Suppositories		X
	1.2.1.13 Tablets		X
	1.2.1.14 Transdermal patches		X
	1.2.1.15 Intraruminal devices		X
	1.2.1.16 Veterinary premixes		X
	1.2.1.17 Other non-sterile medicinal products		X
	<i>1.2.2 Batch certification only (in case you would have dosage forms in this product group contract manufactured)</i>		X
1.3	BIOLOGICAL MEDICINAL PRODUCTS		X
	<i>1.3.1 Biological medicinal products</i>		X
	1.3.1.1 Blood products		X
	1.3.1.2 Immunological products		X
	1.3.1.3 Cell therapy products		X
	1.3.1.4 Gene therapy products		X
	1.3.1.5 Biotechnology products		X
	1.3.1.6 Human or animal extracted products		X
	1.3.1.7 Other biological medicinal products, namely:		X
	<i>1.3.2 Batch certification only (in case you would have dosage forms in this product group contract manufactured; list of product types)</i>		X
	1.3.2.1 Blood products		X
	1.3.2.2 Immunological products		X
	1.3.2.3 Cell therapy products		X
	1.3.2.4 Gene therapy products		X
	1.3.2.5 Biotechnology products		X
	1.3.2.6 Human or animal extracted products		X
	1.3.2.7 Other biological medicinal products		X
1.4	OTHER PRODUCTS OR MANUFACTURING ACTIVITY (ANY OTHER RELEVANT MANUFACTURING ACTIVITY/PRODUCT TYPE THAT IS NOT COVERED ABOVE, E.G. STERILISATION OF ACTIVE SUBSTANCES, MANUFACTURE OF BIOLOGICAL ACTIVE STARTING MATERIALS (WHEN REQUIRED BY NATIONAL LEGISLATION), HERBAL OR HOMEOPATHIC PRODUCTS, BULK OR TOTAL MANUFACTURING, ETC.)		X





	<i>1.4.1 Manufacture of:</i>		X
	1.4.1.1 Herbal medicinal products		X
	1.4.1.2 Homeopathic medicinal products		X
	1.4.1.3 Biological active substances		X
	1.4.1.4 Other		X
	<i>1.4.2 Sterilisation of active substances/excipients/finished product</i>		X
	1.4.2.1 Filtration		X
	1.4.2.2 Dry heat		X
	1.4.2.3 Moist heat		X
	1.4.2.4 Chemical		X
	1.4.2.5 Gamma irradiation		X
	1.4.2.6 Electron beam		X
	<i>1.4.3 Other</i>		X
1.5	PACKAGING ONLY		X
	<i>1.5.1 Primary packing</i>		X
	1.5.1.1 Capsules, hard shell		X
	1.5.1.2 Capsules, soft shell		X
	1.5.1.3 Chewing gums		X
	1.5.1.4 Impregnated matrices		X
	1.5.1.5 Liquids for external use		X
	1.5.1.6 Liquids for internal use		X
	1.5.1.7 Medicinal gases		X
	1.5.1.8 Other solid dosage forms		X
	1.5.1.9 Pressurised preparations		X
	1.5.1.10 Radionuclide generators		X
	1.5.1.11 Semi-solids		X
	1.5.1.12 Suppositories		X
	1.5.1.13 Tablets		X
	1.5.1.14 Transdermal patches		X
	1.5.1.15 Intraruminal devices		X
	1.5.1.16 Veterinary premixes		X
	1.5.1.17 Other non-sterile medicinal products		X
	<i>1.5.2 Secondary packing</i>		X
1.6	QUALITY CONTROL TESTING		X
	<i>1.6.1 Microbiological: sterility</i>		X
	<i>1.6.2 Microbiological: non-sterility</i>		X
	<i>1.6.3 Chemical/Physical</i>		X





	<i>1.6.4 Biological</i>		X
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Any restrictions or clarifying remarks related to the scope of these manufacturing operations

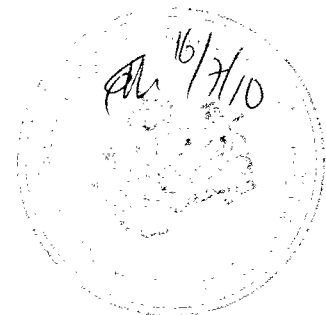




PART 2 – IMPORTATION OF MEDICINAL PRODUCTS	
- authorised importation activities without manufacturing activity;	
- authorised importation activities include storage and distribution unless informed to the contrary.	

		Yes	No
2.1	QUALITY CONTROL TESTING OF IMPORTED MEDICINAL PRODUCTS		X
	<i>2.1.1 Microbiological: sterility</i>		X
	<i>2.1.2 Microbiological: non-sterility</i>		X
	<i>2.1.3 Chemical/Physical</i>		X
	<i>2.1.4 Biological</i>		X
2.2	BATCH CERTIFICATION OF IMPORTED MEDICINAL PRODUCTS	X	
	<i>2.2.1 Sterile products</i>	X	
	2.2.1.1 Aseptically prepared	X	
	2.2.1.2 Terminally sterilised	X	
	<i>2.2.2 Non-sterile products</i>	X	
	<i>2.2.3 Biological medicinal products</i>	X	
	2.2.3.1 Blood products		X
	2.2.3.2 Immunological products		X
	2.2.3.3 Cell therapy products		X
	2.2.3.4 Gene therapy products		X
	2.2.3.5 Biotechnology products	X	
	2.2.3.6 Human or animal extracted products		X
	2.2.3.7 Other biological medicinal products		X
	<i>2.2.4 Other importation activities (any other relevant)</i>	X	
	2.2.4.1 Radiopharmaceuticals		X
	2.2.4.2 Medicinal gases		X
	2.2.4.3 Herbal products	X	
	2.2.4.4 Homeopathic products		X
	2.2.4.5 Biological active starting materials		X
	2.2.4.6 Other		X

Any restrictions or clarifying remarks related to the scope of these manufacturing operations





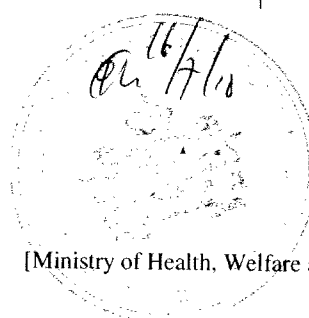
PART 1 – MANUFACTURING OPERATIONS RELATING TO INVESTIGATIONAL MEDICINAL PRODUCTS

- authorised manufacturing operations include total and partial manufacturing (including various processes of dividing up, packaging or presentation), batch release and certification, importation, storage and distribution of specified dosage forms unless informed to the contrary;

- quality control testing and/or release and batch certification activities without manufacturing operations should be specified under the relevant items;

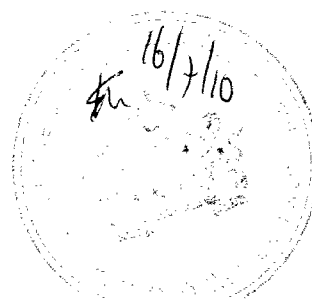
- if the company is engaged in the manufacture of products with special requirements, e.g. radiopharmaceuticals or products containing penicillin, sulphonamides, cytotoxics, cephalosporins, substances with hormonal activity or other potentially hazardous active ingredients, this should be stated under the relevant product type and dosage form.

		Yes	No
1.1	STERILE INVESTIGATIONAL MEDICINAL PRODUCTS		X
	<i>1.1.1 Aseptically prepared (list of dosage forms)</i>		X
	1.1.1.1 Large volume liquids		X
	1.1.1.2 Lyophilisates		X
	1.1.1.3 Semi-solids		X
	1.1.1.4 Small volume liquids		X
	1.1.1.5 Solids and implants		X
	1.1.1.6 Other aseptically prepared products		X
	<i>1.1.2 Terminally sterilised (list of dosage forms)</i>		X
	1.1.2.1 Large volume liquids		X
	1.1.2.2 Semi-solids		X
	1.1.2.3 Small volume liquids		X
	1.1.2.4 Solids and implants		X
	1.1.2.5 Other terminally sterilised prepared products		X
	<i>1.1.3 Batch certification only (in case you would have dosage forms in this product group contract manufactured)</i>		X
1.2	NON-STERILE INVESTIGATIONAL MEDICINAL PRODUCTS		X
	<i>1.2.1 Non-sterile products (list of dosage forms)</i>		X
	1.2.1.1 Capsules, hard shell		X
	1.2.1.2 Capsules, soft shell		X
	1.2.1.3 Chewing gums		X
	1.2.1.4 Impregnated matrices		X
	1.2.1.5 Liquids for external use		X
	1.2.1.6 Liquids for internal use		X
	1.2.1.7 Medicinal gases		X
	1.2.1.8 Other solid dosage forms		X
	1.2.1.9 Pressurised preparations		X





	1.2.1.10 Radionuclide generators		X
	1.2.1.11 Semi-solids		X
	1.2.1.12 Suppositories		X
	1.2.1.13 Tablets		X
	1.2.1.14 Transdermal patches		X
	1.2.1.15 Other non-sterile medicinal products:		X
	<i>1.2.2 Batch certification only (in case you would have dosage forms in this product group contract manufactured)</i>		X
1.3	BIOLOGICAL INVESTIGATIONAL MEDICINAL PRODUCTS		X
	<i>1.3.1 Biological medicinal products</i>		X
	1.3.1.1 Blood products		X
	1.3.1.2 Immunological products		X
	1.3.1.3 Cell therapy products		X
	1.3.1.4 Gene therapy products		X
	1.3.1.5 Biotechnology products		X
	1.3.1.6 Human or animal extracted products		X
	1.3.1.7 Other biological medicinal products		X
	<i>1.3.2 Batch certification only (in case you would have dosage forms in this product group contract manufactured; list of product types)</i>		X
	1.3.2.1 Blood products		X
	1.3.2.2 Immunological products		X
	1.3.2.3 Cell therapy products		X
	1.3.2.4 Gene therapy products		X
	1.3.2.5 Biotechnology products		X
	1.3.2.6 Human or animal extracted products		X
	1.3.2.7 Other biological medicinal products		X
1.4	OTHER INVESTIGATIONAL MEDICINAL PRODUCTS OR MANUFACTURING ACTIVITY		X
	<i>1.4.1 Manufacture of:</i>		X
	1.4.1.1 Herbal products		X
	1.4.1.2 Homeopathic products		X
	1.4.1.3 Biological active starting materials		X
	1.4.1.4 Other		X
	<i>1.4.2 Sterilisation of active substances/excipients/finished product</i>		X
	1.4.2.1 Filtration		X
	1.4.2.2 Dry heat		X
	1.4.2.3 Moist heat		X
	1.4.2.4 Chemical		X
	1.4.2.5 Gamma irradiation		X
	1.4.2.6 Electron beam		X





	<i>1.4.3 Other:</i>		X
1.5	PACKAGING ONLY		X
	<i>1.5.1 Primary packing</i>		X
	1.5.1.1 Capsules, hard shell		X
	1.5.1.2 Capsules, soft shell		X
	1.5.1.3 Chewing gums		X
	1.5.1.4 Impregnated matrices		X
	1.5.1.5 Liquids for external use		X
	1.5.1.6 Liquids for internal use		X
	1.5.1.7 Medicinal gases		X
	1.5.1.8 Other solid dosage forms		X
	1.5.1.9 Pressurised preparations		X
	1.5.1.10 Radionuclide generators		X
	1.5.1.11 Semi-solids		X
	1.5.1.12 Suppositories		X
	1.5.1.13 Tablets		X
	1.5.1.14 Transdermal patches		X
	1.5.1.15 Other non-sterile medicinal products		X
	<i>1.5.2 Secondary packing</i>		X
1.6	QUALITY CONTROL TESTING		X
	<i>1.6.1 Microbiological: sterility</i>		X
	<i>1.6.2 Microbiological: non-sterility</i>		X
	<i>1.6.3 Chemical/Physical</i>		X
	<i>1.6.4 Biological</i>		X

Any restrictions or clarifying remarks related to the scope of these manufacturing operations





PART 2 – IMPORTATION OF INVESTIGATIONAL MEDICINAL PRODUCTS

- authorised importation activities without manufacturing activity;

- authorised importation activities include storage and distribution unless informed to the contrary.

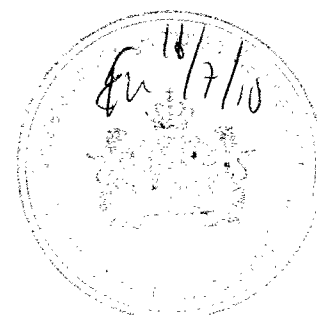
		Yes	No
2.1	QUALITY CONTROL TESTING OF IMPORTED MEDICINAL PRODUCTS		X
	<i>2.1.1 Microbiological: sterility</i>		X
	<i>2.1.2 Microbiological: non-sterility</i>		X
	<i>2.1.3 Chemical/Physical</i>		X
	<i>2.1.4 Biological</i>		X
2.2	BATCH CERTIFICATION OF IMPORTED MEDICINAL PRODUCTS		X
	<i>2.2.1 Sterile products</i>		X
	2.2.1.1 Aseptically prepared		X
	2.2.1.2 Terminally sterilised		X
	<i>2.2.2 Non-sterile products</i>		X
	<i>2.2.3 Biological medicinal products</i>		X
	2.2.3.1 Blood products		X
	2.2.3.2 Immunological products		X
	2.2.3.3 Cell therapy products		X
	2.2.3.4 Gene therapy products		X
	2.2.3.5 Biotechnology products		X
	2.2.3.6 Human or animal extracted products		X
	2.2.3.7 Other biological medicinal products		X
	<i>2.2.4 Other importation activities (any other relevant)</i>		X
	2.2.4.1 Radiopharmaceuticals		X
	2.2.4.2 Medicinal gases		X
	2.2.4.3 Herbal products		X
	2.2.4.4 Homeopathic products		X
	2.2.4.5 Biological active starting materials		X
	2.2.4.6 Other		X

Any restrictions or clarifying remarks related to the scope of these manufacturing operations





ANNEX 3: ADDRESSES OF CONTRACT LABORATORIES	
Proxy Laboratories	Archimedesweg 25, 2333 CM LEIDEN, the Netherlands
SGS Lab. Simon	10 Vieux Chemin du Poete 1301 WAVRE, Belgium





ANNEX 4: QUALIFIED PERSON (QP)

Mr J. Heijmenberg

