COLEGIO DE ESCRIBANOS
CIUDAD DE BUENOS AIRES
CAPITAL FEDERAL - REPUBLICA ARGENTINA

CERTIFICACION DE REPRODUCCIONES
LEY 404

A.N.M.A.
FECHA DE ENTRADA

T 014669178

FABIANA E. ALALÚ
ESCRIBANA
MAT. 4298

Buenos Aires, 08 de NOVIEMBRE de 2013

En mi carácter de escribano Fabiana E. Alalú Titular del Registro Notarial N°1663

CERTIFICO que la reproducción anexa, extendida en OCHO (8)

foja/s, que sello y firmo, es COPIA FIEL de su original, que tengo a la vista, doy fe.

Corresponde a un Certificado N°IT/198-11/H/2013 en Idioma extranjero de la Agencia Italiana de Farmacología.-

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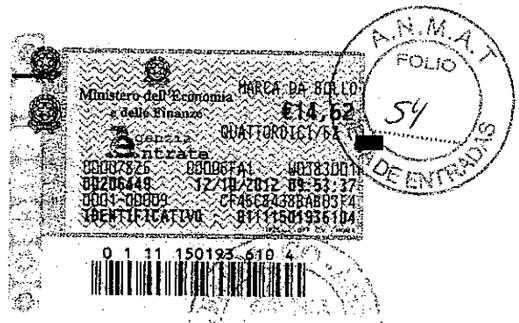

Agenzia Italiana del Farmaco

Certificate No: IT/19-9/H/2013

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER

Part 1

Issued following an inspection in accordance with Art. 111(5) of Directive 2001/83/EC

The competent authority of Italy confirms the following:
The manufacturer NOVARTIS VACCINES AND DIAGNOSTICS S.R.L.
Site address BELLARIA - ROSIA - 53018 SOVICILLE (SI)

Has been inspected under the national inspection programme in connection with manufacturing authorisation no. aM - 97/2012 dated 07/27/2012 in accordance with Art. 40 of Directive 2001/83/EC/ transposed in the following national legislation: D.Lvo 219/2006 art. 50.

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on 02/17/2012 it is considered that it complies with the Good Manufacturing Practice requirements referred to in The principles and guidelines of Good Manufacturing Practice laid down in Directive 2003/94/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, after which time the issuing authority should be consulted.
The authenticity of this certificate may be verified with the issuing authority.

AIFA Italian Medicines Agency
Manufacturing Authorization Office
Via del Tritone, n° 181 - 00187 ROMA (ITALY)
Tel.+390659784489 Fax +390659784312
website: www.agenziafarmaco.it
SIS : 7127

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IDIO
MAT. 79 X - PÚ
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Agenzia Italiana del Farmaco

Part 2

Name and address of the site: NOVARTIS VACCINES AND DIAGNOSTICS S.R.L. - BELLARIA - ROSIA , 53018 SOVICILLE(SI)

Human Medicinal Products

Authorised Operations

Manufacturing Operations (Part 1)
Importation of medicinal products (Part 2)

PART 1 - MANUFACTURING OPERATIONS

1.1	Sterile Products		
	1.1.1	*Aseptically prepared*	
		1.1.1.1	Large volume liquids
		1.1.1.2	Lyophilisates
		1.1.1.4	Small volume liquids
	1.1.2	*Terminally sterilised*	
		1.1.2.3	Small volume liquids
1.2	Non-sterile products		
	1.2.1	*Non-sterile products*	
		1.2.1.6	Liquids for internal use
1.3	Biological medicinal products		
	1.3.1	*Biological medicinal products*	
		1.3.1.2	Immunological products
		1.3.1.5	Biotechnology products

Any restrictions or clarifying remarks related to the scope of these Manufacturing operations:
1.1.1.2 Lyophilisates: Visual inspection, secondary packing, quality control and batch certification;
1.2.1.6 Liquids for internal use: only bulk;
1.3.1.2 Immunological products: Inactivated bacterial vaccine, Viral inactivated vaccine, Viral live vaccine;
1.3.1.5 Biotechnology products: Recombinant proteins/DNA;

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PART 2 - IMPORTATION OF MEDICAL PRODUCTS

2.1	Quality control testing of imported medical 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/authorisation procedures	
	2.2.1	*Sterile products*
		2.2.1.1 Aseptically prepared products
	2.2.3	*Biological medicinal products*
		2.2.3.2 Immunological products

Any restrictions or clarifying remarks related to the scope of these Importing operations:
2.2.3.2 Immunological products: Inactivated bacterial vaccine;

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CAPITAL FEDERAL
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