AGENZIA ITALIANA DEL FARMACO

Ministero dell'Economia e delle Finanze
MARCA DA BOLLO
€16,00
SEDICI/00
Agenzia Entrate
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00001553 18/04/2020 09:35:39
4578-00088 E0B31C2AD7DACB77
IDENTIFICATIVO : 01122016280356

AGENZIA ITALIANA DEL FARMACO

Certificate No: IT/38/H/2020

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 ISTITUTO DI FISIOLOGIA CLINICA DEL CNR - OFFICINA FARMACEUTICA DELL'ISTITUTO DI FISIOLOGIA CLINICA
Site address VIA MORUZZI,1 - 56124 PISA (PI)

Has been inspected under the national inspection programme in connection with manufacturing authorisation no. aM - 22/2020 dated 02/11/2020 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 11/22/2019, 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
GMP Inspections and Manufacturing Authorizations of Medicinal Products Office
Via del Tritone, n° 181 - 00187 ROMA (ITALY)
Tel.+390659784410 Fax +390659784312
website: www.agenziafarmaco.it
SIS : 2940

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Part 2

Name and address of the site:	ISTITUTO DI FISIOLOGIA CLINICA DEL CNR - OFFICINA FARMACEUTICA DELL'ISTITUTO DI FISIOLOGIA CLINICA - VIA MORUZZI, 1, 56124 PISA (PI)

Human Medicinal Products

Authorised Operations

Manufacturing Operations (Part 1)

PART 1 - MANUFACTURING OPERATIONS

1.1	**Sterile Products**	
	1.1.1	*Aseptically prepared*
	1.1.1.4	Small volume liquids Special Requirements: Radiopharmaceuticals
	1.1.3	*Batch certification*
1.5	**Packaging**	
	1.5.2	*Secondary packing*
1.6	**Quality control testing**	
	1.6.3	*Chemical/Physical*
	1.6.4	*Biological*

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

1.1.1.4 Small volume liquids: only radiopharmaceuticals:[18F]-Fluodeoxyglucose;
1.1.3 Batch certification: only aseptically prepared radiopharmaceuticals ;
1.5.2 Secondary packing: only radiopharmaceuticals;
1.6.3 Chemical/Physical: only radiopharmaceuticals;
1.6.4 Biological: LAL Test, only radiopharmaceuticals;

AGENZIA ITALIANA DEL FARMACO

Rome, 02/28/2020

Name and signature of the authorised person of the Competent Authority of Republic of Italy

Renato Massimi
GMP Inspections and Manufacturing Authorizations of Medicinal Products Office

E' copia conforme all'originale composta di n. 3 fogli
Roma li 05/03/2020

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