Certificate No: IT/153/H/2024

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 ITEL TELECOMUNICAZIONI S.R.L.
Site address VIA ANTONIO LABRIOLA ZONA INDUSTRIALE SNC - 70037 RUVO DI PUGLIA (BA)

Has been inspected under the national inspection programme in connection with manufacturing authorisation no. aM - 111/2024 dated 07/17/2024 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 04/12/2024, 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.+390659784357 Fax +390659784312
website: www.agenziafarmaco.it
SIS : 3327

PC
GMP

Part 2

Name and address of the site:	ITEL TELECOMUNICAZIONI S.R.L. - VIA ANTONIO LABRIOLA ZONA INDUSTRIALE SNC , 70037 RUVO DI PUGLIA(BA)

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
	1.1.2	*Terminally sterilised*
	1.1.2.3	Small volume liquids Special Requirements: Radiopharmaceuticals
	1.1.3	*Batch certification*
1.5	**Packaging**	
	1.5.2	*Secondary packing*
1.6	**Quality control testing**	
	1.6.1	*Microbiological: sterility*
	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: 18F-Fluorodeoxyglucose;18F-Flutemetamol; 18F-Fluorocholine, 18F-Fluorodopa, 18F-Florbetaben, 18F-PSMA-1007, 18F-JK-PSMA-7;

1.1.2.3 Small volume liquids: 18F-Fluorodeoxyglucose; 18F-Sodium fluoride;

1.1.3 Batch certification: only radiopharmaceuticals;

1.5.2 Secondary packing: only radiopharmaceuticals;

1.6.1 Microbiological: sterility: only radiopharmaceuticals;
1.6.3 Chemical/Physical: also radionuclidic purity; only radiopharmaceuticals;
1.6.4 Biological: endotoxin test; only radiopharmaceuticals ;

Name and address of the site: ITEL TELECOMUNICAZIONI S.R.L. - VIA ANTONIO LABRIOLA ZONA INDUSTRIALE SNC , 70037 RUVO DI PUGLIA(BA)

Human Medicinal Products

Authorised Operations

Manufacturing Operations (Part 1)

PART 1 - MANUFACTURING OPERATIONS OF INVESTIGATIONAL MEDICINAL PRODUCTS

1.1	**Sterile investigational medical 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**	
	1.6.1	*Microbiological: sterility*
	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: 18F Radiopharmaceuticals;
1.1.3 Batch certification: only radiopharmaceuticals;
1.5.2 Secondary packing: only radiopharmaceuticals;
1.6.1 Microbiological: sterility: only radiopharmaceuticals;
1.6.3 Chemical/Physical: also radionuclidic purity; only radiopharmaceuticals;

1.6.4 Biological: endotoxin test; only radiopharmaceuticals;

Rome, 07/17/2024

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

DEL VECCHIO ANGELA
AIFA - AGENZIA ITALIANA DEL FARMACO
Dirigente
19.07.2024 12:04:50
GMT+00:00

Angela Del Vecchio
GMP Inspections and Manufacturing Authorizations of Medicinal Products Office

STAMP DUTY PAID ACCORDING TO THE CURRENT ITALIAN LAW

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