AGENZIA ITALIANA DEL FARMACO

MARCA DA BOLLO
Ministero dell'Economia e delle Finanze
€16,00
SEDICI/00

0 1 19 003273 670 6

Certificate No: IT/17/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 L. MOLTENI & C. DEI F.LLI ALITTI SOCIETA' DI ESERCIZIO S.P.A.
Site address S.S.67 (TOSCO ROMAGNOLA) LOCALITÀ GRANATIERI - 50018 SCANDICCI (FI)

Has been inspected under the national inspection programme in connection with manufacturing authorisation no. aM - 13/2020 dated 02/03/2020 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 11/23/2018, 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.

"SANTFARM PRIM"

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 : 549

PC
GMP

Digitally signed by Harea Ștefan
Date: 2021.09.20 15:59:40 EEST
Reason: MoldSign Signature
Location: Moldova

AGENZIA ITALIANA DEL FARMACO

Part 2

Name and address of the site:	L. MOLTENI & C. DEI F.LLI ALITTI SOCIETA' DI ESERCIZIO S.P.A. - S.S.67 (TOSCO ROMAGNOLA) LOCALITÀ GRANATIERI , 50018 SCANDICCI(FI)

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*
		1.1.1.4 Small volume liquids
	1.1.2	*Terminally sterilised*
		1.1.2.3 Small volume liquids
	1.1.3	*Batch certification*
1.2	**Non-sterile products**	
	1.2.1	*Non-sterile products*
		1.2.1.5 Liquids for external use
		1.2.1.6 Liquids for internal use
		1.2.1.11 Semi-solids
		Special Requirements:
		Other : hormones or substances with hormonal activity
	1.2.2	*Batch certification*
1.5	**Packaging**	
	1.5.1	*Primary packing*
		1.5.1.5 Liquids for external use
		1.5.1.6 Liquids for internal use
		1.5.1.11 Semi-solids
	1.5.2	*Secondary packing*
1.6	**Quality control testing**	
	1.6.1	*Microbiological: sterility*

	1.6.2	*Microbiological: non-sterility*
	1.6.3	*Chemical/Physical*
	1.6.4	*Biological*

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

1.6.4 Biological: LAL test;

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 only (list of product types)**	
	2.2.1	*Sterile products*
	2.2.1.2	Terminally sterilised
	2.2.2	*Non-sterile products*
2.3	**Other importation activities**	
	2.3.1	*Site of physical importation*
	2.3.2	*Importation of intermediate which undergoes further processing*

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

2.1.4 Biological: LAL test;

2.2.1.2 Terminally sterilised : small and large volume liquids imported from Switzerland;Implants;

2.2.2 Non-sterile products: liquids for internal use;

2.3.2 Importation of intermediate which undergoes further processing: subcutaneous sterile implant from USA;

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AGENZIA ITALIANA DEL FARMACO

Name and address of the site:	MAGAZZINO - VIUZZO DEL PISCETTO/VIA DEL PADULE-AREA SALVADORI - 50018 - SCANDICCI (FI)

Human Medicinal Products

Authorised Operations

Manufacturing Operations (Part 1)

PART 1 - MANUFACTURING OPERATIONS

1.4	**Other products or manufacturing activity**	
	1.4.3	*Others*

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

1.4.3 Others: warehousing;

Name and address of the site:	L. MOLTENI & C. DEI F.LLI ALITTI SOCIETA' DI ESERCIZIO S.P.A. - S.S.67 (TOSCO ROMAGNOLA) LOCALITÀ GRANATIERI , 50018 SCANDICCI(FI)

Human Medicinal Products

Authorised Operations

Manufacturing Operations (Part 1)

PART 1 - MANUFACTURING OPERATIONS OF INVESTIGATIONAL MEDICINAL PRODUCTS

1.1	**Sterile investigational medical products**	
	1.1.3	*Batch certification*
1.2	**Non-sterile investigational medical products**	
	1.2.1	*Non-sterile products*
	1.2.1.6	Liquids for internal use
	1.2.2	*Batch certification*
1.5	**Packaging**	
	1.5.1	*Primary packing*

	1.5.1.6	Liquids for internal use
1.6	**Quality control testing**	
	1.6.2	*Microbiological: non-sterility*
	1.6.3	*Chemical/Physical*

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

1.1.3 Batch certification: products terminally sterilised;

Rome, 02/11/2020

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

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