English version of

AUTORIZZAZIONE ALLA PRODUZIONE
AUTHORIZATION FOR THE PRODUCTION
aM - 152/2018

Issued by

Agenzia Italiana del Farmaco (AIFA)
AREA ISPEZIONI E CERTIFICAZIONI
Ufficio Autorizzazioni Officine

Italian Medicines Agency (AIFA)
INSPECTION AND CERTIFICATION AREA
Manufacturing Authorization Office

This translation is prepared by Eurofins Biolab srl.
The original Italian document testifies the authenticity of this document.

Approved by
QA Manager & QP
Patrizia Custode

Rome, 6th December, 2018

N° aM - 152/2018

THE MANAGER

GIVEN art 48 of the Decree 30th September 2003 No.269, converted into Law 24th November 2003, n. 326, establishing the Italian Drug Agency;

GIVEN Legislative Decree 24th April 2006, No.219 entitled "Implementation of Directive 2001/83/CE (and subsequent amending directives) on the Community code on medicinal products for human use and Directive 2003/94/CE;

GIVEN Legislative Decree 24th June 2003, No.211 entitled "Implementation of Directive 2001/20/CE on the achievement of good clinical practice in clinical trials of Medicinal Products for clinical use;

GIVEN Legislative Decree 6th November 2007, No.200 entitled "Implementation of Directive 2005/28/CE related to principles and detailed guidelines for good clinical practice of Human Medicinal Products under experimentation as well as requirements for authorization to manufacture or importation of Human Medicinal Products;

GIVEN Ministerial Decree 18th March 1996 which predicts the transmission, by the authorized companies, of punctual and complete documentation related to the activities of production of each Officina Farmaceutica;

GIVEN official records relating to authorizations for the production of the Medicinal Products previously issued for the Company EUROFINS BIOLAB SRL;

GIVEN the application received by the same pharmaceutical company, on 10/07/2018, protocol No.79067, for the own Officina Farmaceutica located in VIMODRONE (MI), VIA B. BUOZZI, 2, concerning the new laboratory MIT authorization and the installation of TDS IS-600 isolator in the local B 13.2 (laboratory Micro Pharma 2- Class D) in order to perform sterility test;

GIVEN the outcome of the inspection carried out in the period 2nd ÷ 5th October 2018 at Officina Farmaceutica of the pharmaceutical company located in VIMODRONE (MI), VIA B. BUOZZI, 2;

GIVEN the documentation received on 12th November 2018, protocol No.123767, concerning the answer to deviations encountered during the inspection and containing declaration of renunciation of isolator implementation;

GIVES AUTHORIZATION TO

The company

EUROFINS BIOLAB SRL VIA BUOZZI, 2 20090 - VIMODRONE (MI) Tax code: 03765750157

for the production of MEDICINAL PRODUCTS in its own “Officina Farmaceutica”:

EUROFINS BIOLAB SRL VIA BUOZZI, 2 20090 - VIMODRONE (MI)

as reported in the attached production Authorization N° aM – 152/2018 issued on 6th December, 2018.

The following authorization is granted exclusively under the legislation for the manufacturing of Medicinal Products and in no event shall relieve the holder from compliance with any other applicable legislation.

The attached Authorization is issued in two originals; one remains as official document of this Administration and one is notified to the authorized Company and supersedes the previous authorizations.

Rome, 6th December, 2018

The Manager

(Renato Massimi)

MANUFACTURING AUTHORIZATION

1. Authorization number	aM - 152/2018
2. Authorization holder	EUROFINS BIOLAB SRL
3. Address of the production site	EUROFINS BIOLAB SRL - VIA B. BUOZZI, 2 20090- VIMODRONE (MI)
4. Legal address of the authorization holder	VIA B. BUOZZI, 2 20090- VIMODRONE (MI)
5. Authorization purpose and medicinal products	Manufacturing operations: Attachment 1 Part 1. Manufacturing operations of Investigational Medicinal Products: Attachment 2 Part 1.
6. Authorization references	2001/83/CE Directive, 2001/20/CE Directive, 2005/28/CE Directive, acknowledged by Legislative Decree 24th April 2006, No. 219 and following modifications and integrations, Legislative Decree 24th June 2003, No. 211, Legislative Decree 6th November 2007, No. 200.
7. Name of the manager of the Authority responsible for the release of manufacturing authorization	Dott. Renato Massimi
8. Signature	*(stamp & signature)*
9. Date	6th December, 2018
10. Attachments	Attachment 1 and Attachment 2 Attachment 5 (Name of the Qualified Person) Attachment 7 (Date of the inspection related with the Authorization release, purpose of the last inspection)

ATTACHMENT N°1

AUTHORIZATION PURPOSE

Name and Address of the site	EUROFINS BIOLAB SRL - VIA B. BUOZZI, 2 20090- VIMODRONE (MI)

Human medicinal products

Authorized Operations
Manufacturing Operations (Part 1)

PART 1 - MANUFACTURING OPERATIONS

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*

Restrictions or clarifications to manufacturing operations
Quality controls for active substances release;
1.6.4 Biological: in vivo, in vitro, LAL test

ATTACHMENT N°2

AUTHORIZATION PURPOSE

Name and Address of the site	EUROFINS BIOLAB SRL - VIA B. BUOZZI, 2 20090- VIMODRONE (MI)

Human medicinal products

Authorized Operations
Manufacturing Operations (Part 1)

PART 1 - MANUFACTURING OPERATIONS OF INVESTIGATIONAL MEDICINAL PRODUCTS

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*

Restrictions or clarifications to manufacturing operations
Quality controls for active substances release;
1.6.4 Biological: in vivo, in vitro, LAL test

ATTACHMENT N°5

Name/s of Qualified Person	- PATRIZIA CUSTODE born in FOGGIA on 30th July 1961 - MARIELLA PIREDDA born in NUORO on 3rd January 1971

ATTACHMENT N°7

Date of the inspection related with the Authorization release	5th October 2018
Purpose of the last inspection	General revision

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