



Agenzia Italiana del Farmaco
AIFA



Certificate No: IT/56-3/H/2017

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 S.I.I.T. S.R.L. SERVIZIO INTERNAZIONALE IMBALLAGGI TERMOSALDANTI
Site address VIA L. ARIOSTO, 50/60 - 20090 TREZZANO SUL NAVIGLIO (MI)

Has been inspected under the national inspection programme in connection with manufacturing authorisation no. aM - 217/2016 dated 12/15/2016 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 07/08/2016, 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. +390659784489 Fax +390659784312
website: www.agenziafarmaco.it
SIS : 1364

LPC
GMP



Agenzia Italiana del Farmaco

AIFA

Part 2

Name and address of the site:

S.I.I.T. S.R.L. SERVIZIO INTERNAZIONALE
IMBALLAGGI TERMOSALDANTI - VIA L. ARIOSTO
50/60 , 20090 TREZZANO SUL NAVIGLIO(MI)

Human Medicinal Products

Authorised Operations

Manufacturing Operations (Part 1)

PART 1 - MANUFACTURING OPERATIONS

1.2	Non-sterile products
	1.2.1 <i>Non-sterile products</i>
	1.2.1.1 Capsules, hard shell
	1.2.1.8 Other solid dosage forms
	1.2.1.13 Tablets
	1.2.2 <i>Batch certification</i>
1.3	Biological medicinal products
	1.3.1 <i>Biological medicinal products</i>
	1.3.1.7 Other biological medicinal products
1.5	Packaging
	1.5.1 <i>Primary packing</i>
	1.5.1.1 Capsules, hard shell
	1.5.1.8 Other solid dosage forms
	1.5.1.13 Tablets
	1.5.2 <i>Secondary packing</i>

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

No quality control testing;

1.2.1.8 Other solid dosage forms: granules, powders;

1.3.1.7 Other biological medicinal products: Probiotics. Powders only (1.2.1.8);

AIFA Italian Medicines Agency
GMP Inspections and Manufacturing Authorizations of Medicinal Products Office
Via del Tritone, n° 181 - 00187 ROMA (ITALY)
Tel.+390659784489 Fax +390659784312
website: www.agenziafarmaco.it
SIS : 1364

LPC
GMP



Agenzia Italiana del Farmaco

AIFA

Name and address of the site:

LABORATORIO CONTROLLO QUALITA' - VIA
CANOVA, 16/18 - 20090 - TREZZANO SUL NAVIGLIO
(MI)

Human Medicinal Products

Authorised Operations

Manufacturing Operations (Part 1)

PART 1 - MANUFACTURING OPERATIONS

1.6	Quality control testing
1.6.2	Microbiological: non-sterility
1.6.3	Chemical/Physical

Name and address of the site: MAGAZZINO - VIA CANOVA, 5 - 20090 - TREZZANO
SUL NAVIGLIO (MI)

Human Medicinal Products

Authorised Operations

Manufacturing Operations (Part 1)

PART 1 - MANUFACTURING OPERATIONS

1.4	Other products or manufacturing activity
1.4.3	Others: storage areas

Rome, 04/05/2017

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

Dott. Giuseppe Pimpinella
GMP Inspections and Manufacturing
Authorizations of Medicinal Products Office

AIFA Italian Medicines Agency
GMP Inspections and Manufacturing Authorizations of Medicinal Products Office
Via del Tritone, n° 181 - 00187 ROMA (ITALY)
Tel. +390659784489 Fax +390659784312
website: www.agenziafarmaco.it
SIS: 1364

LPC
GMP



Valentina Vernazza
NOTAIO

===== COPIA CONFORME =====

Certifico io sottoscritta Valentina Vernazza, notaio in Milano, iscritto presso il Collegio Notarile dei Distretti Riuniti di Milano, Busto Arsizio, Lodi, Monza e Varese, che la presente è copia conforme all'originale del documento, a me esibito e restituito all'interessato, in tre fogli oltre il presente. =====

Si rilascia per gli usi consentiti dalla legge. =====
Milano, via privata Cesare Battisti n. 2, venti aprile duemiladiciassette. =====



Valentina Vernazza



6 U Z 1022 // 2017

Beglaubigung

Die Übereinstimmung vorstehender Ablichtung
mit der beglaubigten Abschrift wird hiermit beglaubigt.

Freiburg i. Br., den 19. Mai 2017

Notariat 6 Freiburg i.Br.

Fahnenbergplatz 4, D-79098 Freiburg i.Br.



Pohl, Notar

Apostille

(Convention de La Haye du 5 octobre 1961)

1. Land: Bundesrepublik Deutschland

Diese öffentliche Urkunde

2. ist unterschrieben von Justizrat Pohl

3. in seiner Eigenschaft als Notar

4. sie ist versehen mit dem Siegel
des Notariats Freiburg

Bestätigt

5. in Freiburg i. Br.

6. am 26.05.2017

7. durch Präsident des Landgerichts Neff

8. unter Nr. E 910 - 947/17

9. Stempel

10. Unterschrift

