MINISTRY OF HEALTH
NATIONAL AGENCY FOR MEDICINES
AND MEDICAL DEVICES OF ROMANIA
48, Av. Sănătescu St, Sector 1, 011478 Bucharest
Tel: +4021-317.11.00
Fax: +4021-316.34.97
www.anm.ro

Certificate number : 6137

CERTIFICATE OF A PHARMACEUTICAL PRODUCT[1]

This certificate conforms to the format recommended by the World Health Organization
(explanatory notes are attached)

No. of Certificate: **6137**

Exporting (certifying) country: **ROMANIA**

Importing (requesting) country: **REPUBLIC of MOLDOVA**

1. Name, dosage form and strenght of the product:

ARGININA-SORBITOL 50 mg/ml + 100 mg/ml solution for infusion

1.1. Active ingredient(s)[2] and amount(s) per 1000 ml[3] :

L-argininum hydrochloridum	***50,00 g***
Sorbitolum	***100,00 g***

For complete composition including excipients, see attached [4].

1.2. Is this product licensed to be placed on the market for use in the exporting country?[5]
☑ *Yes* ☐ *No*

1.3.Is this product actually on the market in the exporting country?
☑ *Yes* ☐ *No*

If the answer to 1.2. is **yes**, continue with section 2A and omit section 2B. If the answer to 1.2 is **no**, omit section 2A and continue with section 2B[6] .

2.A.1. Marketing Authorisation number[7]: **11784**

Date of Marketing Authorisation: **15 May 2019**

AGENȚIA NAȚIONALĂ A MEDICAMENTULUI ȘI A DISPOZITIVELOR MEDICALE DIN ROMÂNIA
MINISTERUL SĂNĂTĂȚII
PREȘEDINTE

Digitally signed by Chirtoacă Iurie
Date: 2022.01.05 10:41:28 EET
Reason: MoldSign Signature
Location: Moldova

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2.A.2. Product licence holder (name and address):

Name: **INFOMED FLUIDS S.R.L.**

Address: **B-dul Theodor Pallady Nr. 50, Sector 3, București – Romania**

2. A.3. Status of product licence holder[8] :

a/b/c

2. A.3.1 For categories b and c the name and address of the manufacturer producing the dosage form is[9] :

2. A.4. Is a summary basis for approval appended?[10]

☐ *Yes* ☑ *No*

2. A.5. Is the attached, officially approved product information complete and consonent with the licence?[11]

☐ *Yes* ☑ *Not Provided*

The applicant assumes the whole responsability for the accuracy of the translation of the text from Romanian into English.

2.A.6. Applicant for certificate, if different from licence holder (name and address)[12] : **No**

3. Does the certifying authority arrange for periodic inspection of the manufacturing plant in which the dosage form is produced:

☑ *Yes* ☐ *No* ☐ *Not Applicable*

3.1. Periodicity of routine inspections (years): **3 years**

3.2. Has the manufacture of this type of dosage form been inspected?

☑ *Yes* ☐ *No*

3.3. Do the facilities and operations conform to GMP as recommended by the World Health Organization?[15]

☑ *Yes* ☐ *No* ☐ *Not Applicable*

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4. Does the information submitted by the applicant satisfy the certifying authority on all aspects of the manufacture of the product?[16]

☑ *Yes* ☐ *No*

Address of certifying authority:
48 Av. Sănătescu Street, sector 1, 011478 Bucharest - Romania

Telephone Number: **+ 0040-021-317 11 02**

Fax Number: + **0040-021-316 34 97**

E-mail: **www.anm.ro**

Name of authorized person: **Marius Daniel ȘIȘU**

Signature:

Stamp and date:

0 1 NOV. 2019

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Complete composition for 1000 ml solution for infusion

L-argininum hydrochloridum	***50.00 g***
Sorbitolum	***100.00 g***
Water for injections	*Until to 1000,00 ml*

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Explanatory notes

[1] This certificate, which is in the format recommended by WHO, establishes the status of the pharmaceutical product and of the applicant for the certificate in the exporting country. It is for a single product only since manufacturing arrangements and approved information for different dosage forms and different strengths can vary.

[2] Use, whenever possible, International Nonproprietary Names (INNs) or national onproprietary names.

[3] The formula (complete composition) of the dosage form should be given on the certificate or be appended.

[4] Details of quantitative composition are preferred but their provision is subject to the agreement of the product-licence holder.

[5] When applicable, append details of any restriction applied to the sale, distribution or administration of the product that is specified in the product licence.

[6] Sections 2A and 2B are mutually exclusive.

[7] Indicate, when applicable, if the licence is provisional, or the product has not yet been approved.

[8] Specify whether the person responsible for placing the product on the market:

(a) manufactures the dosage form;

(b) packages and/or labels a dosage form manufactured by an independent company; or

(c) is involved in none of the above.

[9] This information can only be provided with the consent of the product-licence holder or, in the case of non-registered products, the applicant. Non-completion of this section indicates that the party concerned has not agreed to inclusion of this information. It should be noted that information concerning the site of production is part of the product licence. If the production site is changed, the licence has to be updated or it is no longer valid.

[10] This refers to the document, prepared by some national regulatory authorities, that summarizes the technical basis on which the product has been licensed.

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[11] This refers to product information approved by the competent national regulatory authority, such as Summary Product Characteristics (SPC).

[12] In this circumstance, permission for issuing the certificate is required from the product-licence holder. This permission has to be provided to the authority by the applicant.

[13] Please indicate the reason that the applicant has provided for not requesting registration.

(a) the product has been developed exclusively for the treatment of conditions — particularly tropical diseases - not endemic in the country of export;

(b) the product has been reformulated with a view to improving its stability under tropical conditions;

(c) the product has been reformulated to exclude excipients not approved for use in pharmaceutical products in the country of import;

(d) the product has been reformulated to meet a different maximum dosage limit for an active ingredient;

(e) any other reason, please specify.

[14] Not applicable means the manufacture is taking place in a country other than that issuing the product certificate and inspection is conducted under the aegis of the country of manufacture.

[15] The requirements for good practices in the manufacture and quality control of drugs referred to in the certificate are those included in the thirty-second report of the Expert Committee on Specifications for Pharmaceutical Preparations, WHO Technical Report Series No. 823, 1992, Annex 1. Recommendations specifically applicable to biological products have been formulated by the WHO Expert Committee on Biological Standardization (WHO Technical Report Series, No. 822, 1992, Annex 1).

[16] This section is to be completed when the product-licence holder or applicant conforms to status (b) or (c) as described in note 8 above. It is of particular importance when foreign contractors are involved in the manufacture of the product. In these circumstances the applicant should supply the certifying authority with information to identify the contracting parties responsible for each stage of manufacture of the finished dosage form, and the extent and nature of any controls exercised over each of these parties.