EudraGMDP

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National Agency for Medicines and Medical Devices of Romania

CERTIFICATE NUMBER :***005/2019/RO***

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER *(1), (2)*

Part 1

Issued following an inspection in accordance with :
Art. 15 of Directive 2001/20/EC

The competent authority of Romania confirms the following:

The manufacturer :***INFOMED FLUIDS S.R.L.***

Site address : ***Str. Theodor Pallady nr. 50, sector 3, Bucureşti, cod 032266, Romania***

Has been inspected under the national inspection programme in connection with manufacturing authorisation no. ***21F*** in accordance with Art. 13 of Directive 2001/20/EC transposed in the following national legislation:
art. 48 from Minister of Public Health Order no. 904/2006 for approval of Regulations relating the implementation of Good clinical practice in the conduct of clinical trials on medicinal products of human use

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on ***2018-09-28*** , it is considered that it complies with :

- The principles and guidelines of Good Manufacturing Practice laid down in Directive 2003/94/EC *(3)*

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. However, this period of validity may be reduced or extended using regulatory risk management principles by an entry in the Restrictions or Clarifying remarks field. This certificate is valid only when presented with all pages and both Parts 1 and 2.
The authenticity of this certificate may be verified in EudraGMDP. If it does not appear, please contact the issuing authority.

Digitally signed by Chirtoacă Iurie
Date: 2021.05.14 14:40:52 EEST
Reason: MoldSign Signature
Location: Moldova

(1) The certificate referred to in paragraph 111(5) of Directive 2001/83/EC and 80(5) of Directive 2001/82/EC, shall also be required for imports coming from third countries into a Member State.
(2) Guidance on the interpretation of this template can be found in the Help menu of EudraGMDP database.
(3) These requirements fulfil the GMP recommendations of WHO.

Part 2

Human Investigational Medicinal Products

1 MANUFACTURING OPERATIONS
1.1 Sterile products
1.1.2 Terminally Sterilised (processing operations for the following dosage forms) 1.1.2.1 Large volume liquids *1.1.3 Batch certification*
1.5 Packaging
1.5.2 Secondary packaging
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*

Clarifying remarks (for public users) :
total manufacturing operations for sterile products – large volumes parenteral – terminally sterilized, are carried out only in Line 1

2019-01-16

Name and signature of the authorised person of the Competent Authority of Romania

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National Agency for Medicines and Medical Devices
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