Agen□ia Na□ională a Medicamentului □i a Dispozitivelor Medicale din România

CERTIFICATE NUMBER: ***011/2021/RO***

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER [1, 2]

Part 1

Issued following an inspection in accordance with :

The competent authority of Romania confirms the following:
The manufacturer: ***INFOMED FLUIDS S.R.L.***
Site address: ***Bulevardul 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. 40 of Directive 2001/83/EC.

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:

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.

[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.*

Digitally signed by Chirtoacă Iurie
Date: 2022.09.30 17:18:34 EEST
Reason: MoldSign Signature
Location: Moldova

Part 2

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*

2 IMPORTATION OF MEDICINAL PRODUCTS	
2.1	**Quality control testing of imported medicinal 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 of imported medicinal products**
	2.2.1 Sterile products 2.2.1.1 Aseptically prepared 2.2.1.2 Terminally sterilised
2.3	**Other importation activities**
	2.3.1 Site of physical importation
	2.3.2 Importation of intermediate which undergoes further processing

Clarifying remarks (for public users)

total manufacturing operations are carried out for sterile products – large volumes parenterals – terminally sterilized - packaged in glass vials and in PVC/non PVC bags(volumes from 50ml to 5000ml);Building A1 – partial manufacturing operations–secondary packaging are performed, for imported medicinal products mentioned in Annex 8; Building A1 – storage of raw materials;Building A3 – finished products warehouse; Building B2 – storage of primary and secondary packaging materials; storage of finished products is carried out also in the storage spaces belonging to H.ESSERS LOGISTICS SRL from Comuna Bolintin - Deal,Str.DC147,nr.2,Jude□ul Giurgiu, cod po□tal 087015 according to Warehousing and Logistics Services Agreement and the Quality Agreement Logistical Services to it. Importation of medicinal products from InfoRLiFe SA,Swizerland, manufactured up to bulk ampules,for batch certification/batch release,storage and distribution; this Certificate is valid up to September 2021

2021-08-24

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

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Confidential
National Agency for Medicines and Medical Devices of Romania
Tel:***Confidential***
Fax:***Confidential***