РЕПУБЛИКА БЪЛГАРИЯ
Изпълнителна агенция по лекарствата
REPUBLIC OF BULGARIA
Bulgarian Drug Agency

СЕРТИФИКАТ ЗА ДОБРА ПРОИЗВОДСТВЕНА ПРАКТИКА

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER

№ BG/GMP/2017/112

Digitally signed by Chitic Vlad
Date: 2023.06.12 15:38:16 EEST
Reason: MoldSign Signature
Location: Moldova

Част 1
Part 1

Издаден в резултат на извършена проверка на производител на лекарствени продукти съгласно чл. 111, ал. 5 от Директива 2001/83/ЕС.
Issued following an inspection in accordance with Art. 111(5) of Directive 2001/83/EC.

Изпълнителна агенция по лекарствата на Република България удостоверява следното:
Bulgarian Drug Agency confirms the following:

Производителят на лекарствени продукти:
The manufacturer:
CinnaGen Co.
Адрес на обекта:
Site address:
(3rd Sq. Simindasht Industrial Area, Karaj, Alborz), Plot 74, Corner of the 3rd Sq., Simindasht Nongovernmental Industrial, Fardis Township, Alborz Province, 316533155, Islamic Republic of Iran
Manufacturing site: SiminDasht 2 (SD2)

бе проверен във връзка с разрешение за употреба на лекарствени продукти, произведени извън Европейската икономическа зона съгласно чл. 111(4) от Директива 2001/83/ЕС, транспонирани в националното законодателство на Република България с чл. 269, ал.4 от ЗЛПХМ.
Has been inspected in connection with marketing authorisation(s) listing manufacturers located outside of the European Economic Area in accordance with Art. 111(4) of Directive 2001/83/EC transposed in the following national legislation of Bulgaria Art.269(4) of Medicinal Products for Human Use Act.

При последната проверка на дружеството, проведена на 08/11/2017 бе установено, че условията на производство са в съответствие с принципите и изискванията за добра производствена практика, посочени в Директива 2003/94/ЕС/.
From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on 08/11/2017, it is considered that it complies with principles and guidelines of Good Manufacturing Practice laid down in Directive 2003/94/EC/.

Настоящият сертификат отразява условията на местата за производство по време на проверката, посочена по-горе и не трябва да се счита, че отразява действителното състояние на производителя, ако са изминали повече от три години от датата на проверката. Въпреки това, този срок на валидност може да бъде намален или удължен чрез използване оценка на риска, което се посочва в полето „Ограниченията или забележки".
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.

Сертификатът е валиден само, когато е представен с всички страници и двете Части 1 и 2.
This certificate is valid only when presented with all pages and both Parts 1 and 2.

Истинността на този сертификат може да бъде проверена в EudraGMP. Ако не е въведен, Моля свържете се с издаващия орган.
The authenticity of this certificate may be verified in EudraGMP. If it does not appear, please contact the issuing authority

Част 2
Part 2

☒ **Лекарствени продукти за хуманна употреба**/*Human medicinal products*

	1. ПРОИЗВОДСТВЕНИ ДЕЙНОСТИ/ *MANUFACTURING OPERATIONS*
1.1	**Стерилни продукти**/*Sterile products*
	1.1.1 Асептично изготвени/*Aseptically prepared*
	1.1.1.2 Лиофилизати/*Lyophilisates*
	1.1.1.4 Течности с малък обем/*Small volume liquids*
1.3.	**Биологични лекарствени продукти**/*Biological medicinal products*
	1.3.1 Биологични лекарствени продукти/*Biological medicinal products*
	1.3.1.5 Биотехнологични продукти/ *Biotechnology products*
1.4.	**Други продукти или производствени дейности**/*Other products or manufacturing activity*
	1.4.2 Стерилизация на активни вещества/помощни вещества/краен продукт/ *Sterilisation of active substances/excipients/finished product:*
	1.4.2.1 Филтриране/*Filtration*
1.5.	**Опаковане**/*Packaging*
	1.5.2 Вторично опаковане/*Secondary packing*
1.6.	**Качествен контрол**/*Quality control testing*
	1.6.1 Микробиологични: стерилни/*Microbiological: sterility*
	1.6.3 Химични /физични/*Chemical/Physical*
	1.6.4 Биологични/*Biological*

Ограничения или забележки, имащи връзка с обхвата на тези производствени дейности:
Any restrictions or clarifying remarks related to the scope of this manufacturing operation:

Тази инспекция покри само производствен обект SiminDasht 2 (SD2).
т. 1.3.1.5. включва производство на биологични активни вещества и дозирани форми, съдържащи биологично активни вещества.
This inspection covered the Manufacturing site: SiminDasht 2 (SD2) only.
p. 1.3.1.5 includes manufacture of biological active substances and dosage forms containing biological active substance.

29/12/2017

Доц. Асена Стоименова, дф
Assoc. Prof. Assena Stoimenova, PhD, MScPharm, MPH
Изпълнителен Директор
Executive Director
Изпълнителна агенция по лекарствата
Bulgarian Drug Agency

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COMAC MEDICAL
EXPERTS IN CLINICAL RESEARCH

ИЗПЪЛНИТЕЛНА АГЕНЦИЯ
ПО ЛЕКАРСТВАТА
1303 СОФИЯ, ул. „Д. Груев" №8
Регистрационен индекс и дата
ИАЛ 45994 21-10-2022

COMAC MEDICAL LTD.
R N BG16-0005F/21.10.22

To the attention of
Bogdan Kirilov, MPharm
Executive Director
Bulgarian Drug Agency

21 October 2022
Sofia

Reference: Response to a letter issued by the BDA with ref. number ИАЛ-43015/04-10-2022, regarding a request for information in regards to GMP certificates (BG/GMP/2017/112; BG/GMP/2019/164; BG/GMP/2020/175) of the manufacturer CinnaGen Group, Iran.

Ref. number in BDA: ИАЛ-28045 / 03.07.2017

Dear Mr. Kirilov,

With the current letter, on behalf of the manufacturer CinnaGen Group, we would like to inform you that since it is stated in the letter issued by the BDA with ref. number ИАЛ-43015/04-10-2022, that the GMP certificates of sites located outside the EEA are considered automatically extended until the end of 2023, therefore CinnaGen Group does not require an inspection to be carried out.

Thank you in advance for your time to review this letter.

I remain at your disposal, should you have any further questions.

Sincerely,
Vladislav Dobrinov
Regulatory Affairs Group
Comac Medical Ltd.

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Bulgarian Drug Agency

CERTIFICATE NUMBER: ***BG/GMP/2017/112***

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

Part 1

Issued following an inspection in accordance with :

The competent authority of Bulgaria confirms the following:
The manufacturer: ***CinnaGen Co.***
Site address: ***(3rd Sq.,Simindasht Industrial Area, Karaj, Alborz), Plot 74, Corner of the 3rd Sq., Simindasht Nongovernmental Industrial, Manufacturing site: SiminDasht 2 (SD2), Fardis Township, Alborz Province, 3165933155, Iran, Islamic Republic of***

Has been inspected in connection with marketing authorisation(s) listing manufacturers located outside of the European Economic Area in accordance with Art. 111(4) of Directive 2001/83/EC.

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on ***2017-11-08***, 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.

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[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

1 MANUFACTURING OPERATIONS	
1.1	**Sterile products**
	1.1.1 Aseptically prepared (processing operations for the following dosage forms) 1.1.1.2 Lyophilisates 1.1.1.4 Small volume liquids
1.3	**Biological medicinal products (list of product types)**
	1.3.1 Biological medicinal products (list of product types) 1.3.1.5 Biotechnology products
1.4	**Other products or manufacturing activity**
	1.4.2 Sterilisation of active substance/ excipients/ finished product 1.4.2.1 Filtration
1.5	**Packaging**
	1.5.2 Secondary packaging
1.6	**Quality control testing**
	1.6.1 Microbiological: sterility *1.6.3 Chemical/Physical* *1.6.4 Biological*

4. Other Activities - Active Substances:

This inspection covered the Manufacturing site: SiminDasht 2 (SD2) only. p. 1.3.1.5 includes manufacture of biological active substances and dosage forms containing biological active substance.

2017-12-29

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

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Confidential
Bulgarian Drug Agency
Tel:***Confidential***
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