State Institute For Drug Control

CERTIFICATE NUMBER: ***sukls103349/2021***

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

Part 1

Issued following an inspection in accordance with
Art. 111(5) of Directive 2001/83/EC as amended

The competent authority of Czechia confirms the following:
The manufacturer: ***HEATON k.s.***
Site address: ***areál společnosti Movianto Česká republika, s.r.o., Podolí 78e, Podolí, 664 03, Czechia***

Has been inspected under the national inspection programme in connection with manufacturing authorisation no. ***sukls99158/2019*** 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 ***2021-06-18***, 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. Updates to restrictions or clarifying remarks can be identified through the EudraGMDP website (http://eudragmdp.ema.europa.eu/). 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 Art. 111(5) of Directive 2001/83/ECis also applicable to importers.*

[2] *Guidance on the interpretation of this template can be found in the Interpretation of the Union format for GMP certificate.*

[3] *These requirements fulfil the GMP recommendations of WHO.*

Part 2

Human Medicinal Products

1 MANUFACTURING OPERATIONS	
1.1	**Sterile products**
	1.1.3 Batch certification
1.2	**Non-sterile products**
	1.2.2 Batch certification
1.6	**Quality control testing**
	1.6.3 Chemical/Physical

2 IMPORTATION OF MEDICINAL PRODUCTS	
2.1	**Quality control testing of imported medicinal products**
	2.1.3 Chemical/Physical
2.2	**Batch certification of imported medicinal products**
	2.2.2 Non-sterile products
2.3	**Other importation activities**
	2.3.1 Site of physical importation

Clarifying remarks (for public users)

1.6.3 Chemical/Physical - Physical only 2.1.3 Chemical/Physical - Physical only

2021-08-30

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

---

Confidential
State Institute for Drug Control
Tel: ***Confidential***
Fax: ***Confidential***

State Institute For Drug Control

CERTIFICATE NUMBER: ***sukls269232/2022***

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

Part 1

Issued following an inspection in accordance with
Art. 111(5) of Directive 2001/83/EC as amended

The competent authority of Czechia confirms the following:
The manufacturer: ***Heaton k.s.***
Site address: ***Podoli 78e, Podoli, 664 03, Czechia***
Additional details on units inspected: ***Areál společnosti Movianto Česká republika, s.r.o.***
OMS Organisation Id. / OMS Location Id.: ***ORG-100002884*** / ***LOC-100001478***

Has been inspected under the national inspection programme in connection with manufacturing authorisation no. ***sukls85302/2022*** 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 ***2023-01-11***, it is considered that it complies with:

- The principles and guidelines of Good Manufacturing Practice laid down in Directive (EU) 2017/1572 and Commission Delegated Regulation (EU) 2017/1569 [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. Updates to restrictions or clarifying remarks can be identified through the EudraGMDP website (http://eudragmdp.ema.europa.eu/). 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 Art. 111(5) of Directive 2001/83/ECis also applicable to importers.*

[2] *Guidance on the interpretation of this template can be found in the Interpretation of the Union format for GMP certificate.*

[3] *These requirements fulfil the GMP recommendations of WHO.*

Part 2

Human Medicinal Products

1 MANUFACTURING OPERATIONS	
1.1	**Sterile products**
	1.1.3 Batch certification
1.2	**Non-sterile products**
	1.2.2 Batch certification
1.6	**Quality control testing**
	1.6.3 Chemical/Physical

2 IMPORTATION OF MEDICINAL PRODUCTS	
2.1	**Quality control testing of imported medicinal products**
	2.1.3 Chemical/Physical
2.2	**Batch certification of imported medicinal products**
	2.2.2 Non-sterile products
2.3	**Other importation activities**
	2.3.1 Site of physical importation

Clarifying remarks (for public users)

1.6.3 Chemical/Physical - Physical only 2.1.3 Chemical/Physical - Physical only

2023-04-03

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

---

Confidential
State Institute For Drug Control
Tel:***Confidential***
Fax:***Confidential***

National Agency For The Safety Of Medicine And Health Products

CERTIFICATE NUMBER: ***2023_HPF_FR_060***

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

Part 1

Issued following an inspection in accordance with
Art. 111(5) of Directive 2001/83/EC as amended

The competent authority of France confirms the following:
The manufacturer: ***Cenexi***
Site address: ***17 Rue De Pontoise, Osny, 95520, France***
OMS Organisation Id. / OMS Location Id.: ***ORG-100011846*** / ***LOC-100021736***

Has been inspected under the national inspection programme in connection with manufacturing authorisation no. ***2023_014_1_2*** in accordance with Art. 61 of Regulation (EU) No 536/2014 and Art. 40 of Directive 2001/83/EC.

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on ***2022-12-14***, it is considered that it complies with:

- The principles and guidelines of Good Manufacturing Practice laid down in Directive (EU) 2017/1572 and Commission Delegated Regulation (EU) 2017/1569 [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. Updates to restrictions or clarifying remarks can be identified through the EudraGMDP website (http://eudragmdp.ema.europa.eu/). 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 Art. 111(5) of Directive 2001/83/ECis also applicable to importers.*

[2] *Guidance on the interpretation of this template can be found in the Interpretation of the Union format for GMP certificate.*

[3] *These requirements fulfil the GMP recommendations of WHO.*

Part 2

Human Medicinal Products

1 MANUFACTURING OPERATIONS	
1.2	**Non-sterile products**
	1.2.1 Non-sterile products (processing operations for the following dosage forms) 1.2.1.1 Capsules, hard shell Special Requirements 7 Other: Hormones(en) 1.2.1.13 Tablets Special Requirements 7 Other: Hormones(en)
	1.2.2 Batch certification
1.3	**Biological medicinal products (list of product types)**
	1.3.1 Biological medicinal products (list of product types) 1.3.1.2 Immunological products 1.3.1.6 Human or animal extracted products
1.5	**Packaging**
	1.5.1 Primary Packaging 1.5.1.1 Capsules, hard shell Special Requirements 7 Other: Hormones(en) 1.5.1.13 Tablets Special Requirements 7 Other: Hormones(en)
	1.5.2 Secondary packaging
1.6	**Quality control testing**
	1.6.2 Microbiological: non-sterility *1.6.3 Chemical/Physical*

2 IMPORTATION OF MEDICINAL PRODUCTS	
2.1	**Quality control testing of imported medicinal products**
	2.1.2 Microbiological: non-sterility *2.1.3 Chemical/Physical*
2.2	**Batch certification of imported medicinal products**
	2.2.2 Non-sterile products

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)

1.2.1.13: includes also sugar coated tablets and film coated tablets - Signatory: Mrs Florence Descamps-Delesalle, head of the pharmaceutical product inspection and counterfeiting fight department --- The ANSM does not issue paper copies of good practice certificates.

2023-04-25

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

---

Confidential
National Agency For The Safety Of Medicine And Health Products
Tel:***Confidential***
Fax:***Confidential***