No.:	-
On:	20.9.2024
File No.:	ÚSKVBL/12451/2024/POD Our reg. No.: ÚSKVBL/16427/2024/INS
Handled by:	Mgr. Jiří Dobiaš
Tel.:	541 518 278
E-mail:	dobias@uskvbl.cz
Date:	11.12.2024
Note:	data report hphtvkq

DYNTEC spol. s r. o.

Pražská 328

411 55 Terezín

Permission No.: 617/2024/RHV

DECISION ON AUTHORIZATION CHANGE FOR MANUFACTURE OF VETERINARY MEDICINAL PRODUCTS

Institute for State Control of Veterinary Biologicals and Medicines located in Brno (hereinafter as „Veterinary institute“) as the competent administrative authority pursuant to Section 16, paragraph 2, letter a) point 2. and letter m) of Act No. 378/2007 Coll., on medicinal products and on amendments to certain related acts, as amended (hereinafter as „Act on Medicines“), **issues** in accordance with the provisions of Section 67 of Act No. 500/2004 Coll., Administrative Procedure Code, as amended (hereinafter as „Administration Code“) in the procedure for an application for a change in the manufacturing authorization for veterinary medicinal products, delivered on 20.9.2024, **this**

AUTHORIZATION CHANGE

for manufacture of veterinary medicinal products

The Veterinary Institute, in accordance with Article 92 of Regulation (EU) 2019/6 of the European Parliament and of the Council of 11 December 2018 on veterinary medicinal products and in accordance with Section 63(6) of the Act on Medicinal Products, amends the manufacturing authorisation No. 561/2021/RHV granted to DYNTEC spol. s r. o. by a Decision of reg. No. ÚSKVBL/13304/2021/INS file No. ÚSKVBL/11503/2021/POD from 01.10.2021, as follows:

- **Manufacture is permitted in new manufacture facilities**
  - new storage facilities for primary packaging material (building N)

therefore, **DYNTEC spol. s r. o. IČ 475 48 002 with the address Pražská 328, 411 55 Terezín** is permitted to produce veterinary medicinal products in the following scope

Addresses of all manufacture sites	**I. : Pražská 328, 411 55 Terezín**
Type and scope of permitted manufacture	see Annex No. 1 (total of 1 page), section A) Activities carried out by the manufacturing authorisation holder

Addresses of contractual manufacture sites, type and scope of contractual activities	-
Addresses of contractual quality control sites, type and scope of contractual activities	**Kladská 1032/44C, 500 03 Hradec Králové** **Chotouň 90, 254 01 Pohoří**
	type and scope see Annex No. 1 (total of 1 page) section B) Activities provided under contract
Qualified person	**MVDr. Mgr. Ladislav Pažout** **Ing. Pavla Žáková**
Date of inspection in manufacture site and its scope	The manufacturer is authorized to operate only with equipment and in premises approved by the inspection group during the on-site inspection carried out on 30.9.-03.10.2024 (system periodic inspection + change inspection) and in compliance with the conditions set out in the GMP Inspection Protocol of reg. No. ÚSKVBL/16166/2024/INS from 05.12.2024 (system periodic inspection + change inspection).
Manufactured/supplied products	The manufacturing authorization is valid only for the manufacturing sites and dosage forms specified in the application of reg. No. ÚSKVBL/12451/2024/POD from 20.9.2024.

Decision is issued in compliance with Compilation of Union Procedures on Inspections and Exchange of Information as amended and valid from 01.08.2024.

J u s t i f i c a t i o n

Justification in compliance with § 68 paragraph 4 of Administrative Code is not stated because the request for a change in the manufacturing authorization for medicinal products was fully granted.

N o t i f i c a t i o n

An appeal against this decision may be filed with the Institute for State Control of Veterinary Biologicals and Medicines, pursuant to Section 81 et seq. of the Administrative Code, within 15 days from the date of notification of this decision. The appeal shall be decided by the Central Veterinary Administration of the State Veterinary Administration.

MVDr. Jiří Bureš
Digitálně podepsal MVDr. Jiří Bureš
Datum: 2024.12.16 11:01:14 +01'00'

MVDr. Jiří Bureš
Head of the Service Office
of the Institute for State Control of Veterinary Biologicals and Medicines

Annex No. 1 for Decision on change of permission to produce veterinary medicinal products No. 617/2024/RHV, file No.: ÚSKVBL/12451/2024/POD, reg. No.: ÚSKVBL/16427/2024/INS
(The Annex forms an integral part of the abovementioned Decision)

Section A) Activities carried out by the manufacturing authorisation holder – DYNTEC spol. s r. o.

I. Manufacture site: Pražská 328, 411 55 Terezín

☒ **Veterinary medicinal products**	
Part 1 – MANUFACTURE OPERATIONS	
1.1	**Sterile products**
	1.1.1 Prepared aseptically 1.1.1.1 Bulk liquid pharmaceutical forms 1.1.1.2 Lyophilised 1.1.1.4 Low-volume liquid pharmaceutical forms
	1.1.2. Terminally sterilized 1.1.2.3 Low-volume liquid pharmaceutical forms
	1.1.3 Batch release
1.3	**Biological products**
	1.3.1 Biological medicinal products 1.3.1.1 Blood derivatives 1.3.1.2 Immunological products
	1.3.2 Batch release 1.3.2.1 Blood derivatives 1.3.2.2 Immunological products
1.5	**Packing**
	1.5.2 Secondary packing
1.6	**Quality control**
	1.6.1 Microbiological – sterility testing *1.6.2 Microbiological – non-sterile medicinal products* *1.6.3 Chemical/physical* *1.6.4 Biological*

Any restriction or clarification regarding the scope of manufacturing operations: 1.3.1.2. Immunological products: manufacture of bacterial, viral, autogenous vaccines and immunosera

xxx

Section B) Activities provided under contract

ITEST plus, s r. o., Kladská 1032/44C, 500 03 Hradec Králové	
1.6	**Quality control**
	1.6.4 Biological

Any restrictions or explanations regarding the scope of contractual operations: Any restrictions or explanations regarding the scope of contractual operations: none

xxx

BIOPHARM, Research institute of biopharmacy and veterinary medicines a.s., Chotouň 90, 254 01 Pohoří	
1.6	**Quality control**
	1.6.3 Chemical/physical

Any restrictions or explanations regarding the scope of contractual operations: none

xxx

END Annex No. 1

Permission no.: 561/2021/RHV

DECISION on change of the permission to produce veterinary medicinal products

Institute for State Control of Veterinary Biologicals and Medicines, based in Brno (hereinafter the "Institute") as a relevant administrative body according to the § 16 paragraph 2 letter a) point 2 of the Act no. 378/2007 Coll., on Pharmaceuticals and on changes of some related acts (hereinafter "Act no. 378/2007 Coll., on Pharmaceuticals"), **issues** according to the § 63 of the Act no. 378/2007 Coll., on Pharmaceuticals, this

PERMISSION

to produce veterinary medicinal products

in the following range and under the following conditions:

1. Operator:

DYNTEC spol. s r. o.
Company ID: 475 48 002

2. Registered office of the operator:

Pražská 328
411 55 Terezín

3. Permission to produce no. 561/2021/RHV is granted for premises and equipment used by the manufacturer at the address:

Pražská 328, 411 55 Terezín

4. Range of permitted activity including activities provided under the contract in the area of manufacturing and quality control of veterinary medicinal products is stated in **Annex no. 1** to this permission. Annex no. 1 is an integral part of this permission.

5. According to the § 64 letter a) of the Act no. 378/2007 Coll., on Pharmaceuticals, the Qualified Person is:

MVDr. Mgr. Ladislav Pažout

Ing. Pavla Žáková

6. The manufacturer is obliged to follow the relevant provisions of the Act no. 378/2007 Coll., on Pharmaceuticals, Decree no. 229/2008 Coll., on Manufacturing and distribution of Pharmaceuticals (hereinafter "Implementing decree") and instructions issued by the Institute for State Control of Veterinary Biologicals and Medicines.

7. Holder of the permission is obliged, according to the § 64 letter i) of the Act no.378/2007 Coll., on Pharmaceuticals, to allow the officers of the Institute to perform official supervision according to the § 16 paragraph 2 letter e) of the Act no. 378/2007 Coll., on Pharmaceuticals and is obliged to respect the imposed measures according to the § 16 paragraph 2 letter c) and d) of the Act no. 378/2007 Coll., on Pharmaceuticals.

8. The permission is granted for an indefinite period. It may be suspended or cancelled according to the § 63 paragraph 8 of the Act no. 378/2007 Coll., on Pharmaceuticals. Obligations may be imposed to the holder of the Permission to produce veterinary medicinal products even after the entry into the force of this decision. The original Permission to produce veterinary medicinal products issued by the Institute on 01.10.2018 with reg. no. 510/2018/RHV expires on the effective date of this Decision.

9. The manufacturer is authorised to operate only with the equipment and in the premises approved by the inspection group during the inspection performed on 1.9. – 2.9.2021 and with respect to the conditions set in the Protocol on inspection of GMP ref. no. Ú S K V B L / 13218/2021/INS of 30.09.2021.

Statement of the reasons:

Based on the *Decision on change of permission to produce medicinal products* issued by the Institute on 01.10.2018 under reg. no. 510/2018/RHV,

application for a change delivered to the State Control of Veterinary Biologicals and Medicines on 25.08.2021, with ref. no. ÚSKVBL/11503/2021/POD, file number ÚSKVBL/11503/2021/POD submitted according to the § 63, paragraph 6 of the Act no. 378/2007 Coll., on Pharmaceuticals, and the implementing decree,

payment of administrative fee according to the Act no. 634/2004 Coll., on administrative fees, as amended (item 98),

payment of the costs of professional actions performed on a request according to the valid tariff of the State Control of Veterinary Biologicals and Medicines, item I-05 paid on 19.08.2021,

changes of classification of production activities published in "Compilation of Community Procedures" in accordance with Directive 2004/28/EC,

submitted documentation demonstrating compliance with the principles of good manufacturing practice under the provisions of implementing decree and

result of the inspection performed on 1.9. – 2.9.2021, according to the provisions of implementing decree

the Institute found that the applicant fulfilled the requirements for the production of veterinary medicinal products set by the Act no. 378/2007 Coll., on Pharmaceuticals and its implementing regulations and instructions of the Institute, and issued this Permission to produce veterinary medicinal products.

Advice on appeal:

It is possible to submit appeal against this decision within the limit of 15 days from the day of its delivery to the State Veterinary Administration of the Czech Republic through the Institute.

In Brno on 01.10.2021 *Stamp* *Signature*
MVDr. Jiří Bureš
head of service office

List of Annexes:
Annex no. 1: Range of permitted activity (1 page)

Annex no. 1 to the Decision on change of permission to produce veterinary medicinal products no. 561/2021/RHV

A) Activities performed by the holder of permission to produce – DYNTEC spol. s r. o.

☒ Veterinary medicinal products	
Part 1 – Production operations	
1.1	**Sterile products**
	1.1.1 Prepared aseptically 1.1.1.1 Bulk liquid pharmaceutical forms 1.1.1.2 Lyophilised 1.1.1.4 Low-volume liquid pharmaceutical forms
	1.1.2 Terminally sterilized 1.1.2.3 Low-volume liquid pharmaceutical forms
	1.1.3 Batch release
1.3	**Biological products**
	1.3.1 Biological medicinal products 1.3.1.1 Blood derivatives 1.3.1.2 Immunological products
	1.3.2 Batch release 1.3.2.1 Blood derivatives 1.3.2.2 Immunological products
1.5	**Packing**
	1.5.2 Secondary packing
1.6	**Quality control**
	1.6.1 Microbiological – sterility testing
	1.6.2 Microbiological – non-sterile medicinal products
	1.6.3 Chemical/physical
	1.6.4 Biological

Any restriction or clarification regarding the scope of manufacturing operations:
1.3.1.2. Immunological products: production of bacterial, viral, autogenous vaccines and immunosera

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B) Activities provided under contract

ITEST Plus s.r.o., Kladská 1032, Hradec Králové Company ID: 620 61 828	
1.6	**Quality control**
	1.6.4 Biological

BIOPHARM, Research institute of biopharmacy and veterinary medicines a.s., Jílové u Prahy, Pohoří – Chotouň 90, Company ID: 463 56 606	
1.6	**Quality control**
	1.6.3 Chemical/physical
