ÚSKVBL
Ústav pro státní kontrolu veterinárních biopreparátů a léčiv

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
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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

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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

ÚSKVBL
Ústav pro státní kontrolu veterinárních biopreparátů a léčiv

Spis. zn.: ÚSKVBL/2697/2025/INS
Naše č.j.: ÚSKVBL/2697/2025/INS
Vyřizuje: Mgr. Jiří Dobiaš
Telefon: 541 518 278
E-mail: dobias@uskvbl.cz
Datum: 24.02.2025
Poznámka: Datová zpráva hphtvkq

DYNTEC spol. s r.o.

Pražská 328

411 55 Terezín

Informace o povolení k výrobě veterinárních léčivých přípravků reg. číslo 617/2024/RHV

Information about manufacturing authorisation for veterinary medicinal products reg. no. 617/2024/RHV

Ústav pro státní kontrolu veterinárních biopreparátů a léčiv (ÚSKVBL) jako správní orgán České republiky příslušný podle § 16 odst. 2 písm. a) bod 2 a písm. m) zákona č. 378/2007 Sb., o léčivech a o změnách některých souvisejících zákonů, ve znění pozdějších předpisů a v souladu s článkem 92 nařízení Evropského Parlamentu a Rady (EU) 2019/6 ze dne 11. prosince 2018 o veterinárních léčivých přípravcích, potvrzuje, že výrobce **DYNTEC spol. s r.o.** (Pražská 328, 411 55 Terezín, Česká republika) **je držitelem platného povolení k výrobě veterinárních léčivých přípravků, jehož aktuální kompletní znění a rozsah jsou vydány pod reg. číslem 617/2024/RHV**. Slovo „ZMĚNA“ v nadpisu aktuálně platného znění povolení pouze blíže specifikuje, že nové znění bylo vydáno v rámci řízení o změně původního znění povolení, následuje však kompletní rozsah povolení, který je platný samostatně, bez nutnosti dokládat předchozí znění (předchozí znění povolení k výrobě veterinárních léčivých přípravků evidované pod reg. číslem 561/2021/RHV je nahrazeno tímto novým zněním povolení k výrobě veterinárních léčivých přípravků, evidovaným pod reg. číslem 617/2024/RHV).

Institute for the State Control of Veterinary Biologicals and Medicines (ÚSKVBL) as national competent authority of the Czech Republic according to Section 16(2) letter a) item 2 and letter m) of the Act No. 378/2007 Coll., on Pharmaceuticals and Amendments to Several Related Laws in current wording and in accordance with Art. 92) of Regulation (EU) 2019/6 of veterinary medicinal products, confirms that manufacturer ***DYNTEC spol. s r.o.*** *(Pražská 328, 411 55 Terezín, Czech Republic)* ***is holder of valid manufacturing authorisation for veterinary medicinal products, the current complete wording and scope of which are issued under reg. number 617/2024/RHV.*** *The word "CHANGE" in the title of the currently valid wording of the authorisation only specifies in more detail that the new wording was issued as part of the procedure for change the original wording of the authorisation, but the complete scope of the authorisation follows, which is valid separately, without the need to attach previous wording (the previous wording of the manufacturing authorisation for veterinary medicinal products registered under reg. number 561/2021/RHV was replaced by this new wording of the manufacturing authorisation for veterinary medicinal products registered under reg. number 617/2024/RHV).*

MVDr. Jiří Bureš
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MVDr. Jiří Bureš
vedoucí služebního úřadu / *Chief Executive*