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CERTIFICATE OF GDP COMPLIANCE

We certify herewith

that the company **Centre hospitalier universitaire vaudois (CHUV), Rue du Bugnon 21, 1011 Lausanne,** Authorisation No. 511133-102693911 with its site **Centre hospitalier universitaire vaudois (CHUV), Service de pharmacie, Rue du Bugnon 46, 1011 Lausanne, Switzerland**, Site No. 1100213 has been duly authorised to distribute medicinal products resp. API / intermediates according to the table below;

that the company is keeping the required level for Good Distribution Practices for Medicinal Products (GDP) according to the Swiss regulations in force. These regulations are in accordance with the requirements of the following documents:

- Guidelines of the European Commission on Good Distribution Practice of Medicinal Products for Human Use (2013/C 343/01)
- Commission Implementing Regulation (EU) 2021/1248 on Good Distribution Practice for Veterinary Medicinal Products
- Guidelines of the European Commission on Good Distribution Practice of active substances for medicinal products for human use (2015/C 95/01)
- Commission Implementing Regulation (EU) 2021/1280 on Good Distribution Practice for active substances for veterinary medicinal products

that the company is subject to official periodic inspections; the last regular inspection has been performed on **01.02.2023** (dd.mm.yyyy).

No.	*Operation*	*Scope**
S.2	**IMPORT OF MEDICINAL PRODUCTS (WITHOUT LABILE BLOOD PRODUCTS)**	
S.2.1	**Import of non- ready-to-use medicinal products**	
S.2.1.1	Medicinal products (intermediates, without immunological and blood products)	H/V, I
S.2.1.2	Immunological products (intermediates)	H/V, I
S.2.1.3	Blood products (intermediates)	H/V, I
S.2.3	**Import of ready-to-use medicinal products, excluding market release**	
S.2.3.1	Medicinal products (without immunological and blood products)	H/V, I
S.2.3.2	Immunological medicinal products	H/V, I
S.2.3.3	Blood products	H/V, I
S.2.3.4	The import of ready-to-use medicinal products, excluding market release, is restricted to:	
S.2.3.4.1	the import for exclusive re-export	H/V, I
S.2.3.4.3	the import of preparations not authorised in Switzerland on behalf of the ordering healthcare professional	H/V, I
S.2.3.4.4	the import of medicinal products for clinical trials on behalf of the sponsor for subsequent distribution to the trial centres	H/V, I

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No.	*Operation*	*Scope**
S.2.6	**Outsourcing of manufacture of medicinal products as contract giver**	H/V, I
S.4	**WHOLESALE DISTRIBUTION OF MEDICINAL PRODUCTS (WITHOUT LABILE BLOOD PRODUCTS)**	
S.4.1	**Wholesale distribution of non- ready-to-use medicinal products**	
S.4.1.1	Medicinal products (intermediates, without immunological and blood products)	H/V, I
S.4.1.2	Immunological products (intermediates)	H/V, I
S.4.1.3	Blood products (intermediates)	H/V, I
S.4.3	**Wholesale distribution of ready-to-use medicinal products, excluding market release**	
S.4.3.1	Medicinal products (without immunological and blood products)	H/V, I
S.4.3.2	Immunological products	H/V, I
S.4.3.3	Blood products	H/V, I
S.4.6	**Outsourcing of manufacture of medicinal products as contract giver**	H/V, I
S.5	**EXPORT OF MEDICINAL PRODUCTS (WITHOUT LABILE BLOOD PRODUCTS)**	
S.5.1	**Export of non- ready-to-use medicinal products**	
S.5.1.1	Medicinal products (intermediates, without immunological and blood products)	H/V, I
S.5.1.2	Immunological products (intermediates)	H/V, I
S.5.2	**Export of ready-to-use medicinal products**	
S.5.2.1	Medicinal products (without immunological and blood products)	H/V, I
S.5.2.2	Immunological products	H/V, I

* Scope of authorisation:
H/V Human and veterinary medicinal products, without investigational products
V Veterinary medicinal products only, without investigational products
I Human investigational medicinal products
– Not specified

Berne, **10.05.2023** (dd.mm.yyyy)
No. GDP-CH-1004311

Swissmedic, Swiss Agency for Therapeutic Products

J. Büchi

Jacqueline Büchi

Schweizerisches Heilmittelinstitut
Institut suisse des produits thérapeutiques
Istituto svizzero per gli agenti terapeutici
Swiss Agency for Therapeutic Products

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