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CERTIFICATE OF GDP COMPLIANCE

We certify herewith

that the company **Alpinamed AG, 9325 Roggwil TG,** Authorisation No. 511118-102640812 with its site **Alpinamed AG, Werk II, Neuhofstrasse 98, 8590 Romanshorn, Switzerland**, Site No. 1000614 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 **02.09.2021** (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 (without immunological and blood products)	-
S.2.2	**Import of ready-to-use medicinal products, including market release**	
S.2.2.1	Medicinal products (without immunological and blood products)	-
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 (without immunological and blood products)	-
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)	-
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 (without immunological and blood products)	-

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* 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, **29.04.2022** (dd.mm.yyyy)
No. GDP-CH-1003167

Swissmedic, Swiss Agency for Therapeutic Products

J. Büchi

Jacqueline Büchi

Swiss Agency for Therapeutic Products
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