

CERTIFICATE OF GDP COMPLIANCE

We certify herewith

that the company **A.Vogel AG, Grünaustrasse, 9325 Roggwil TG,** Authorisation No. 511618-102651761 with its site **A.Vogel AG, Grünaustrasse, 9325 Roggwil TG, Switzerland**, Site No. 1000497 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 Guidelines on Good Distribution Practice of Medicinal Products for Human Use (2013/C 343/01) of the European Commission and with the requirements of the European GMP Part II (Basic Requirements for Active Substances used as Starting Materials);

No.	Operation	(
S.2	IMPORT OF MEDICINAL PRODUCTS (WITHOUT LABILE BLOOD PRODUCTS)	11
S.2.1 S.2.1.1	Import of non- ready-to-use medicinal products Medicinal products (without immunological and blood products)	I
S.2.2 S.2.2.1	Import of ready-to-use medicinal products, including market release Medicinal products (without immunological and blood products)	
S.2.3 S.2.3.1 S.2.3.4 S.2.3.4.1 S.2.3.4.2	Import of ready-to-use medicinal products, excluding market release Medicinal products (without immunological and blood products) The import of ready-to-use medicinal products, excluding market release, is restricted to: the import for exclusive re-export the import on behalf of the marketing authorisation holder	
S.2.6	Outsourcing of manufacture of medicinal products as contract giver	
S.4	WHOLESALE DISTRIBUTION OF MEDICINAL PRODUCTS (WITHOUT LABILE BLOOD PRODUCTS)	1
S.4.1 S.4.1.1	Wholesale distribution of non- ready-to-use medicinal products Medicinal products (without immunological and blood products)	
S.4.2 S.4.2.1	Wholesale distribution of ready-to-use medicinal products, including market release Medicinal products (without immunological and blood products)	
S.4.6	Outsourcing of manufacture of medicinal products as contract giver	
S.5	EXPORT OF MEDICINAL PRODUCTS (WITHOUT LABILE BLOOD PRODUCTS)	
S.5.1 S.5.1.1	Export of non- ready-to-use medicinal products Medicinal products (without immunological and blood products)	

that the company is subject to official periodic inspections; the last regular inspection has been performed on **20.09.2019** (dd.mm.yyyy).

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

I-303.AA.04-A05e / V1.0 / bja / gme / smi / 01.01.2019

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No.	Operation	
S.5.2	Export of ready-to-use medicinal products	
S.5.2.1	Medicinal products (without immunological and blood products)	
S.5.3	Outsourcing of manufacture of medicinal products as contract giver	

Berne, **11.05.2021** (dd.mm.yyyy) **No. GDP-CH-1002186**

Swissmedic, Swiss Agency for Therapeutic Products

J. Bion.

Jacqueline Büchi

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