

CERTIFICATE OF GDP COMPLIANCE

We certify herewith

that the company **Spirig HealthCare AG, Industriestrasse 30, 4622 Egerkingen**, Authorisation No. 512295-102703454 with its site **Spirig HealthCare AG, Industriestrasse 28/30, 4622 Egerkingen, Switzerland**, Site No. 1106335 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 **06.03.2023** (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
S.2.2	Import of ready-to-use medicinal products, including market release	
S.2.2.1	Medicinal products (without immunological and blood products)	H/V
S.2.2.2	Immunological medicinal products	H/V
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
S.2.3.2	Immunological medicinal products	H/V
S.2.3.4	The import of ready-to-use medicinal products, excluding market release, is restricted to:	
S.2.3.4.2	the import on behalf of the marketing authorisation holder	H/V
S.2.5	Storage of medicinal products by sales representatives	H/V
S.2.6	Outsourcing of manufacture of medicinal products as contract giver	H/V

The authorised importation operations do not include the storage of medicinal products

No.	Operation	Scope*
S.4	WHOLESALE DISTRIBUTION OF MEDICINAL PRODUCTS (WITHOUT LABILE BLOOD PRODUCTS)	
S.4.2	Wholesale distribution of ready-to-use medicinal products, including market release	
S.4.2.1	Medicinal products (without immunological and blood products)	H/V
S.4.2.2	Immunological products	H/V
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
S.4.3.2	Immunological products	H/V
S.4.3.3	Blood products	H/V
S.4.5	Storage of medicinal products by sales representatives	H/V
S.4.6	Outsourcing of manufacture of medicinal products as contract giver	H/V
The authorised wholesale operations do not include the storage of medicinal products		
S.5	EXPORT OF MEDICINAL PRODUCTS (WITHOUT LABILE BLOOD PRODUCTS)	
S.5.2	Export of ready-to-use medicinal products	
S.5.2.1	Medicinal products (without immunological and blood products)	H/V
S.5.2.2	Immunological products	H/V
The authorised exportation operations do not include the storage of medicinal products		

* 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, 17.05.2023 (dd.mm.yyyy)
No. GDP-CH-1004356

Swissmedic, Swiss Agency for
Therapeutic Products



M. Baumann

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