

CERTIFICATE OF GDP COMPLIANCE

We certify herewith

that the company **Lipomed AG, Fabrikmattenweg 4, 4144 Arlesheim**, Authorisation No. 512651-102669084 with its site **Lipomed AG, Fabrikmattenweg 4, 4144 Arlesheim, Switzerland**, Site No. 1000751 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 **13.01.2022** (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.2.3	Import of ready-to-use medicinal products, excluding market release	
S.2.3.1	Medicinal products (without immunological and blood products)	-
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	-
S.2.3.4.2	the import on behalf of the marketing authorisation holder	-
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	-

No.	Operation	Scope*
S.2.6	Outsourcing of manufacture of medicinal products as contract giver	-
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.4.2	Wholesale distribution of ready-to-use medicinal products, including market release	-
S.4.2.1	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	Export of non- ready-to-use medicinal products	-
S.5.1.1	Medicinal products (without immunological and blood products)	-
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	-

* 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, 08.06.2022 (dd.mm.yyyy)
No. GDP-CH-1003265

Swissmedic, Swiss Agency for
Therapeutic Products




Marianne Baumann