

CERTIFICATE OF GDP COMPLIANCE

We certify herewith

that the company **Niveus Pharma GmbH, Archplatz 2, 8400 Winterthur**, Authorisation No. 512143-102639446 with its site **Niveus Pharma GmbH, Archplatz 2, 8400 Winterthur, Switzerland**, Site No. 1103473 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);

that the company is subject to official periodic inspections; the last regular inspection has been performed on **24.11.2020** (dd.mm.yyyy).

No.	Operation
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.2.1.2	Immunological 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.2.3.2	Immunological medicinal 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.2.3.4.3	the import of preparations not authorised in Switzerland on behalf of the ordering healthcare professional
S.2.6	Outsourcing of manufacture of medicinal products as contract giver
	The authorised importation operations do not include the storage of medicinal 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.4.1.2	Immunological 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.4.3.2	Immunological products

No.	Operation
S.4.6	Outsourcing of manufacture of medicinal products as contract giver The authorised wholesale operations do not include the storage of medicinal 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)
S.5.1.2	Immunological products
S.5.2	Export of ready-to-use medicinal products
S.5.2.1	Medicinal products (without immunological and blood products)
S.5.2.2	Immunological products
S.5.3	Outsourcing of manufacture of medicinal products as contract giver The authorised exportation operations do not include the storage of medicinal products

Berne, 21.01.2021 (dd.mm.yyyy)
No. GDP-CH-1001790

Swissmedic, Swiss Agency for
Therapeutic Products



J. Büchi

Jacqueline Büchi