

CERTIFICATE OF GDP COMPLIANCE

We certify herewith

that the company **Rivopharm SA, Centro Insema, 6928 Manno**, Authorisation No. 511351-102608771 with its site **Rivopharm SA, Centro Insema, 6928 Manno, Switzerland**, Site No. 1000456 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 **12.05.2021** (dd.mm.yyyy). Distant assessment

<i>No.</i>	<i>Operation</i>
S.2	IMPORT OF MEDICINAL PRODUCTS (WITHOUT LABILE 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.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.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)

Berne, 22.06.2021 (dd.mm.yyyy)
No. GDP-CH-1002273

Swissmedic, Swiss Agency for
Therapeutic Products



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