

CERTIFICATE OF GDP COMPLIANCE

We certify herewith

that the company **Pistor AG**, **6023 Rothenburg**, Authorisation No. 511815-102679616 with its site **Pistor AG**, **Hasenmoosstrasse 31**, **6023 Rothenburg**, **Switzerland**, Site No. 1103100 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 **12.05.2022** (dd.mm.yyyy).

No.	Operation	Scope*
S.4	WHOLESALE DISTRIBUTION OF MEDICINAL PRODUCTS (WITHOUT LABILE BLOOD PRODUCTS)	17 /
S.4.3	Wholesale distribution of ready-to-use medicinal products, excluding market release	C
S.4.3.1	Medicinal products (without immunological and blood products)	H/V

* Scope of authorisation:

H/V Human and veterinary medicinal products, without investigational products Veterinary medicinal products only, without investigational products

I Human investigational medicinal products

Not specified



Berne, **26.07.2022** (dd.mm.yyyy) **No. GDP-CH-1003386**



Swissmedic, Swiss Agency for Therapeutic Products

€. Orvensper L.

Eva Ehrensperger Murri