

## CERTIFICATE OF GDP COMPLIANCE

We certify herewith

that the company **Dudler Pharma Sàrl, Impasse du Jura 4, 1754 Avry-sur-Matran**, Authorisation No. 512076-102636234 with its site **Dudler Pharma Sàrl, Impasse du Jura 4, 1754 Avry-sur-Matran, Switzerland**, Site No. 1103391 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 **07.09.2022** (dd.mm.yyyy).

No.	Operation	Scope*
<b>S.2</b>	<b>IMPORT OF MEDICINAL PRODUCTS (WITHOUT LABILE BLOOD PRODUCTS)</b>	
	The authorised activities do not include the storage of medicinal products	
<b>S.2.2</b>	<b>Import of ready-to-use medicinal products, including market release</b>	
S.2.2.1	Medicinal products (without immunological and blood products)	-
S.2.2.2	Immunological medicinal products	-
S.2.2.3	Blood products	-
<b>S.4</b>	<b>WHOLESALE DISTRIBUTION OF MEDICINAL PRODUCTS (WITHOUT LABILE BLOOD PRODUCTS)</b>	
	The authorised activities do not include the storage of medicinal products	
<b>S.4.2</b>	<b>Wholesale distribution of ready-to-use medicinal products, including market release</b>	
S.4.2.1	Medicinal products (without immunological and blood products)	-
S.4.2.2	Immunological products	-
S.4.2.3	Blood products	-

No.	Operation	Scope*
<b>S.5</b>	<b>EXPORT OF MEDICINAL PRODUCTS (WITHOUT LABILE BLOOD PRODUCTS)</b>	
The authorised activities do not include the storage of medicinal products		
<b>S.5.2</b>	<b>Export of ready-to-use medicinal products</b>	
S.5.2.1	Medicinal products (without immunological and blood products)	-
S.5.2.2	Immunological products	-
S.5.2.3	Blood 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, 11.11.2022 (dd.mm.yyyy)  
No. GDP-CH-1003723

Swissmedic, Swiss Agency for  
Therapeutic Products



  
Laila Saxena