

## CERTIFICATE OF GDP COMPLIANCE

We certify herewith

that the company **Hänseler AG, Industriestrasse 35, 9100 Herisau**, Authorisation No. 511619-102719232 with its site **Hänseler AG, Industriestrasse 35, 9100 Herisau, Switzerland**, Site No. 1000468 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 **08.09.2023** (dd.mm.yyyy);

that this certificate reflects the status of the premises at the time of the inspection noted above and should not be relied upon to reflect the compliance status if more than five years have elapsed since the date of that inspection.

No.	Operation	Scope*
<b>S.2</b>	<b>IMPORT OF MEDICINAL PRODUCTS (WITHOUT LABILE BLOOD PRODUCTS)</b>	
<b>S.2.1</b>	<b>Import of non- ready-to-use medicinal products</b>	
S.2.1.1	Medicinal products (intermediates, without immunological and blood products)	H/V, I
<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)	H/V, I
<b>S.2.6</b>	<b>Outsourcing of manufacture of medicinal products as contract giver</b>	H/V, I
<b>S.4</b>	<b>WHOLESALE DISTRIBUTION OF MEDICINAL PRODUCTS (WITHOUT LABILE BLOOD PRODUCTS)</b>	
<b>S.4.1</b>	<b>Wholesale distribution of non- ready-to-use medicinal products</b>	
S.4.1.1	Medicinal products (intermediates, without immunological and blood products)	H/V, I
<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)	H/V, I

No.	Operation	Scope*
<b>S.5</b>	<b>EXPORT OF MEDICINAL PRODUCTS (WITHOUT LABILE BLOOD PRODUCTS)</b>	
<b>S.5.1</b>	<b>Export of non- ready-to-use medicinal products</b>	
S.5.1.1	Medicinal products (intermediates, without immunological and blood products)	H/V, I
S.5.1.4	Active substances	H/V, I
<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)	H/V, I

\* Scope of authorisation:

- H/V Prefix S: Human and veterinary medicinal products/ Prefix ST: Human TpP/GT/GVO, without investigational products
- V Veterinary medicinal products only, without investigational products
- I Prefix S: Human investigational medicinal products/ Prefix: ST: Human Investigational TpP/GT/GVO
- Not specified

Bern, **23.04.2024** (dd.mm.yyyy)  
**No. GDP-CH-1005697**

Swissmedic, Swiss Agency for  
 Therapeutic Products



*J. Büchi*

Jacqueline Büchi