

CERTIFICATE OF GMP COMPLIANCE

We certify herewith

that the company **Stiftung Blutspende SRK Aargau - Solothurn, 5000 Aarau**, Authorisation No. 511613-102617137 with its site **Stiftung Blutspende SRK Aargau - Solothurn, c/o Kantonsspital Aarau AG, Tellstrasse, 5000 Aarau, Switzerland,** Site No. 1002212 has been duly authorised to perform the manufacturing activities according to the table below;

that the company is keeping the required level for Good Manufacturing Practices for Medicinal Products (GMP) according to the Swiss regulations in force. These regulations are in accordance with the requirements for good practices in the manufacture and quality control of the Pharmaceutical Inspection Convention/Co-operation Scheme (PIC/S) as well as with The Good Manufacturing Practice requirements referred to in the Agreement of Mutual Recognition between the European Union/Canada and Switzerland;

that the manufacturing plant of the company is subject to official periodic inspections; the last regular inspection was conducted on **15.07.2020** (dd.mm.yyyy).

No.	Operation	Scope*
S.8	BLOOD AND LABILE BLOOD PRODUCTS	1
S.8.1	Collection of blood for transfusion or for the manufacture of medicinal products	
S.8.1.1	Collection of blood for transfusions or for the manufacture of medicinal products (homologous)	7-
S.8.1.2	Collection of blood for autologous transfusions or for the manufacture of autologous blood products	1
S.8.1.3	Collection of blood (for transfusions or for the manufacture of medicinal products) on mobile teams	-
S.8.2	Manufacture of labile blood products	17
S.8.2.1 S.8.2.2	Homologous labile blood products Autologous labile blood products	1

* Scope of authorisation:

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

V Veterinary medicinal products only, without investigational products

Human investigational medicinal products

Not specified

Berne, **23.11.2020** (dd.mm.yyyy) **No. GMP-CH-1001586**



Marianne Baumann

Therapeutic Products

Swissmedic, Swiss Agency for

Schweizerisches Heilmittelinstitut Institut suisse des produits thérapeutiques Istituto svizzero per gli agenti terapeutici Swiss Agency for Therapeutic Products