

CERTIFICATE OF GDP COMPLIANCE

We certify herewith

that the company **SSCB SWISS STEM CELLS BIOTECH SA, Via Pizzamiglio 12, 6833 Vacallo**, Authorisation No. 511334-102633264 with its site **SSCB SWISS STEM CELLS BIOTECH SA, Via Pizzamiglio 12, 6833 Vacallo, Switzerland**, Site No. 1100614 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 **29.07.2020** (dd.mm.yyyy).

No.	Operation
ST.2	IMPORT OF TpP / GT / GMO
ST.2.1	Import of non-ready-to-use TpP as starting material for the manufacture of TpP
ST.2.1.1	intended for autologous transplantation
ST.2.1.2	intended for allogeneic transplantation
ST.2.3	Import of ready-to-use transplant products
ST.2.3.2	excluding market release
ST.2.3.4	Import of ready-to-use tissue engineered products
ST.2.3.4.1	intended for autologous transplantation
ST.2.3.4.2	intended for allogeneic transplantation
ST.2.7	Outsourcing of manufacturing of TpP / GT / GMO as contract giver
ST.4	WHOLESALE TRADING OF TpP / GT / GMO
ST.4.1	Wholesale trading of non-ready-to-use TpP as starting material for the manufacture of TpP
ST.4.1.1	intended for autologous transplantation
ST.4.1.2	intended for allogeneic transplantation
ST.4.3	Wholesale trading of ready-to-use transplant products
ST.4.3.2	excluding market release
ST.4.3.3	Wholesale trading of cell therapy products
ST.4.3.3.1	intended for autologous transplantation
ST.4.3.3.2	intended for allogeneic transplantation
ST.4.3.4	Wholesale trading of tissue products
ST.4.3.4.1	intended for autologous transplantation
ST.4.3.4.2	intended for allogeneic transplantation
ST.4.3.6	Wholesale trading of combination preparations
ST.4.3.6.1	intended for autologous transplantation

No.	Operation
ST.4.3.6.2	intended for allogeneic transplantation
ST.5	EXPORT OF TpP / GT / GMO
ST.5.1	Export of non-ready-to-use TpP as starting material for the manufacture of TpP
ST.5.1.1	intended for autologous transplantation
ST.5.1.2	intended for allogeneic transplantation
ST.5.3	Export of ready-to-use transplant products
ST.5.3.1	Export of ready-to-use cell therapy products
ST.5.3.1.1	for autologous transplantation
ST.5.3.1.2	for allogeneic transplantation
ST.5.3.2	Export of ready-to-use tissue products
ST.5.3.2.1	for autologous transplantation
ST.5.3.2.2	for allogeneic transplantation
ST.5.3.4	Export of ready-to-use combination preparations
ST.5.3.4.1	for autologous transplantation
ST.5.3.4.2	for allogeneic transplantation

Berne, **30.10.2020** (dd.mm.yyyy)
No. GDP-CH-1001482

Swissmedic, Swiss Agency for
Therapeutic Products



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