

CERTIFICATE OF GMP 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 perform the manufacturing activities according to the table below;

that the company is keeping the required level for Good Manufacturing Practices (GMP) for Transplant Products (TpP), Gene Therapy Products (GT) and Genetically Modified Products (GM) 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 **29.07.2020** (dd.mm.yyyy).

No.	Operation	Scope*
1	MANUFACTURE OF TpP / GT / GMO	
1.3.1.7	Manufacture of tissue engineered products	
ST.1.3.1.7.1	Manufacture of intermediate or non-ready-to-use tissue engineered products	
ST.1.3.1.7.1.1	intended for autologous transplantation	H/V, I
ST.1.3.1.7.1.2	intended for allogeneic transplantation	H/V, I
ST.1.3.1.7.2	Manufacture of ready-to-use tissue engineered products	
ST.1.3.1.7.2.1	intended for autologous transplantation	H/V, I
1.6	Quality control testing	
ST.1.6.1	Microbiological: sterility	H/V, I
ST.1.6.2	Microbiological: non-sterility	H/V, I
ST.1.6.4	Biological	H/V, I

* Scope of authorisation:

- H/V Human TpP/GT/GVO, without investigational products
- I Investigational TpP/GT/GVO
- Not specified

Berne, ~~30.10.2020~~ (dd.mm.yyyy)

No. ~~GMP-CH-1001482~~



Swissmedic, Swiss Agency for
Therapeutic Products



Eva Ehrensperger Murri