

CERTIFICATE OF GMP COMPLIANCE

We certify herewith

that the company **Galliker Trasporti SA, Via Industrie, 6592 Sant'Antonino**, Authorisation No. 512246-102645450 with its site **Galliker Trasporti SA, Via Industrie, 6592 Sant'Antonino, Switzerland**, Site No. 1006030 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 **23.12.2020** (dd.mm.yyyy).

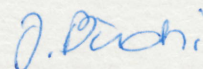
No.	Operation	Scope*
1	MANUFACTURE OF TpP / GT / GMO	H/V
1.5	Packaging of TpP / GT / GMO products	
1.5.2	Secondary packing	

* Scope of authorisation:

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

Berne, **28.12.2020** (dd.mm.yyyy)
No. GMP-CH-1001702

Swissmedic, Swiss Agency for
 Therapeutic Products



Jacqueline Büchi

