swissmedic

CERTIFICATE OF GMP COMPLIANCE

We certify herewith

that the company **Microsynth AG, Schützenstrasse 15, 9436 Balgach,** Authorisation No. 512982-102701044 with its site **Microsynth AG, Schützenstrasse 15, 9436 Balgach, Switzerland,** Site No. 1100216 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 from the knowledge gained during inspection of this manufacturer, the latest of which was conducted on **22.03.2022** (dd.mm.yyyy) , it is considered that it complies with The Good Manufacturing Practice requirements referred to in the Agreement of Mutual Recognition between the European Union/Canada and Switzerland.
That this certificate reflects the status of the manufacturing site at the time of the inspection noted above and should not be relied upon to reflect the compliance status if more than three years have elapsed since the date of that inspection,

The authenticity of this certificate may be verified in EudraGMDP. If it does not appear, please contact the issuing authority.

No.	*Operation*	*Scope**
1	**MANUFACTURE OF TpP / GT / GMO**	
1.6	**Quality control testing**	
1.6.3	Chemical/Physical	H/V, I
1.6.4	Biological	H/V, I
Genetic Analysis		

* Scope of authorisation:
H/V Human TpP/GT/GVO, without investigational products
I Investigational TpP/GT/GVO
– Not specified

Swissmedic | Hallerstrasse 7 | CH-3012 Bern | www.swissmedic.ch | Tel. +41 58 462 02 11 | Fax +41 58 462 02 12

swissmedic

Berne, **15.09.2023** (dd.mm.yyyy)
No. GMP-CH-1004874

Swiss Agency for Therapeutic Products
swissmedic

Swissmedic, Swiss Agency for Therapeutic Products

M. Baumann

Marianne Baumann

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

Swissmedic | Hallerstrasse 7 | CH-3012 Bern | www.swissmedic.ch | Tel. +41 58 462 02 11 | Fax +41 58 462 02 12

swissmedic

CERTIFICATE OF GMP COMPLIANCE

We certify herewith

that the company **Microsynth AG, Schützenstrasse 15, 9436 Balgach, Switzerland**, has been duly authorized to manufacture and distribute active pharmaceutical ingredients (APIs) and medicinal products;

- quality control (chemical, physical) of medicinal products as contract laboratory
- quality control (biological) of medicinal products as contract laboratory

The activities are restricted to the DNA sequencing with the Sanger method

that the company is keeping the required level for good practices in the manufacture of active pharmaceutical ingredients (APIs) and medicinal products 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) and the Directives of the European Commission;

that the manufacturing plant of the company is subject to official periodic inspections; the last regular inspection was conducted on **March 22, 2022**;

that the requirements regarding manufacture and quality control for active pharmaceutical ingredients (APIs) and medicinal products for export are identical to those applicable to active pharmaceutical ingredients (APIs) and medicinal products sold in Switzerland.

Berne, November 11, 2022
No. 22-0056

Swissmedic, Swiss Agency for Therapeutic Products

Dr. Georges Meseguer

Swiss Agency for Therapeutic Products
swissmedic

Swissmedic | Hallerstrasse 7 | CH-3012 Bern | www.swissmedic.ch | Tel. +41 58 462 02 11 | Fax +41 58 462 02 12