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CERTIFICATE OF GMP COMPLIANCE

We certify herewith

that the company **Microsynth AG, Schützenstrasse 15, 9436 Balgach,** Authorisation No. 512981-102701023 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 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/USA and Switzerland;

that from the knowledge gained during inspection of this manufacturer, the latest of which was conducted on **24.06.2024** (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/USA 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 SwissGMDP/EudraGMDP. If it does not appear, please contact the issuing authority.

No.	*Operation*	*Scope**
1	**MANUFACTURE OF MEDICINAL PRODUCTS (WITHOUT LABILE BLOOD PRODUCTS)**	
1.6	**Quality control testing**	
1.6.3	Chemical/Physical	H/V, I
1.6.4	Biological	H/V, I
The approved manufacturing activities are limited to the sequencing of DNA using the Sanger method		
3	**MANUFACTURE OF ACTIVE SUBSTANCES**	
3.6	**Quality control testing**	
3.6.1	Physical / Chemical testing	H/V, I
3.6.4	Biological Testing	H/V, I

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* Scope of authorisation:

H/V	Human and veterinary medicinal products, without investigational products
V	Veterinary medicinal products only, without investigational products
I	Human investigational medicinal products
–	Not specified

Bern, **11.11.2024** (dd.mm.yyyy)
No. GMP-CH-1006329

Swissmedic, Swiss Agency for Therapeutic Products

Swiss Agency for Therapeutic Products
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J. Büchi

Jacqueline Büchi

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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/USA and Switzerland;

that from the knowledge gained during inspection of this manufacturer, the latest of which was conducted on **21.03.2024** (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/USA 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 SwissGMDP/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	Human Investigational TpP/GT/GVO
–	Not specified

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Bern, **04.03.2025** (dd.mm.yyyy)
No. GMP-CH-1006769

Swissmedic, Swiss Agency for Therapeutic Products

M. Baumann
Marianne Baumann

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

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