License no. 512970-102699896

OFFICIAL DECISION

Operating license for Transplant Products (TpP) / Gene Therapy Products (GT) / Genetically Modified Organisms (GMO)

Circumstances

1. Application dated 28 February 2023, number 102699896
2. Applicant: BACHEM AG
3. Reason for the application:
   Initial issue

Legal bases

- Therapeutic Products Act (TPA, SR 812.21)
- Medicinal Products Licensing Ordinance (MPLO; SR 812.212.1)
- Ordinance on the Fees charged by the Swiss Agency for Therapeutic Products (FeeO-Swissmedic, SR 812.214.5)
- Transplantation Act (SR 810.21)
- Transplantation Ordinance (SR 810.211)

Swissmedic has decided the following:

1. Holder of the operating license
   BACHEM AG
   Hauptstrasse 144
   4416 Bubendorf

2. The license is numbered 512970-102699896

3. The license is granted for the following activities:
   - Manufacture of transplant products (TpP) / gene therapy products (GT) / genetically modified organisms (GMO)
   - Import of transplant products (TpP) / gene therapy products (GT) / genetically modified organisms (GMO)
   - Wholesale trading in transplant products (TpP) / gene therapy products (GT) / genetically modified organisms (GMO)
   - Export of transplant products (TpP) / gene therapy products (GT) / genetically modified organisms (GMO)
   - Trading abroad in transplant products (TpP) / gene therapy products (GT) / genetically modified organisms (GMO)

4. Number of operating sites: 1

5. The circumstances described in the annexes apply

6. The license is valid for an unlimited period from 22 May 2023.

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7. Fee: CHF 7600.00

Bern, 22 May 2023

Swissmedic, Swiss Agency for Therapeutic Products

[signed]

Gerda Baeriswyl
Central Dispatch

Your contact:
Inspectorates and Licenses Division
Secretariat tel. no.: +41 58 462 04 55

Information on the right of appeal:
An appeal against this decision may be filed within 30 days of delivery with the Federal Administrative Court (address: Bundesverwaltungsgericht, Postfach, 9023 St. Gallen) (Art. 31 and 33e of the Federal Act of 17 June 2005 on the Federal Administrative Court; SR 173.32). The appeal document should include a request for remedy, the reasons for the remedy being sought with material cited in evidence and the signature of the appellant or the appellant's representative; the disputed decision and the documentation cited in evidence should be enclosed (Art. 52 of the Federal Act of 20 December 1968 on Administrative Procedure; SR 172.021).

Copies for information:
- Regional Medicines Inspectorate of North-Western Switzerland (RMI)
- Cantonal Pharmacist, Basel-Landschaft

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Annex 1

Operating site 1001480

Bachem AG
Hauptstrasse 144
4416 Bubendorf

Qualified Person(s)

QP 1
Dunkel Silke
Dr. rer. nat., chemist

QP 2
Milejski Dawid
Pharmacist

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Approved activities / conditions / restrictions

No.	*Designation*	*Scope**	*QP*
1	**MANUFACTURE OF TpP / GT / GMO**		
1.3.1.8	**Manufacture of other TpP / GT / GMO products**		
ST.1.3.1.8.2	Other: Oligonucleotides: non-sterile active pharmaceutical ingredients	H/V, I	1
1.3.2	**Batch release (technical release)**		
1.3.2.8	Other TpP / GT / GMO products: oligonucleotides: non-sterile active pharmaceutical ingredients	H/V, I	1
1.5	**Packaging of TpP / GT / GMO products**		
1.5.1	Primary packaging		
1.5.1.17	Other non-sterile products: oligonucleotides: non-sterile active pharmaceutical ingredients	H/V, I	1
1.6	**Quality control**		
1.6.2	Microbiological analysis without sterility testing	H/V, I	1
1.6.3	Chemical / Physical	H/V, I	1
S.2	**IMPORT OF TpP / GT / GMO**		
S.2.2	**Import of non-ready-to-use GT/GMO products as starting material for the manufacture of GT/GMO products**		
S.2.2.4	Other: Oligonucleotides: non-sterile active pharmaceutical ingredients	H/V, I	2
S.4	**WHOLESALE TRADING IN TpP / GT / GMO**		
S.4.2	**Wholesale trading in non-ready-to-use GT/GMO products as starting material for the manufacture of GT/GMO products**		
S 4.2.4	Other: Oligonucleotides: non-sterile active pharmaceutical ingredients	H/V, I	2
S.5	**EXPORT OF TpP / GT / GMO**		
S.5.2	**Export of non-ready-to-use GT/GMO products as starting material for the manufacture of GT/GMO products**		
S.5.2.4	Other: Oligonucleotides: non-sterile active pharmaceutical ingredients	H/V, I	2
S.6	**TRADING ABROAD IN TpP / GT / GMO**		
S.6.2	**Trading abroad in non-ready-to-use GT/GMO products, without storage in Switzerland, as starting material for the manufacture of GT/GMO products**		
S.6.2.4	Other: Oligonucleotides: non-sterile active pharmaceutical ingredients	H/V, I	2

*see last page

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Scope of approved activities (for all annexes)

H/V	TpP/GT/GMO for use in human medicine, excluding products for clinical trials
I	TpP/GT/GMO for clinical trials
-	Not specified

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CONFIRMATION

This is to confirm that the English translation of the following document:

Swissmedic
Verfügung Betriebsbewilligung Transplantatprodukte (TpP)/
Gentherapieprodukte (GT)/ Gentechnisch veränderte Organismen (GVO)
Bewilligung Nr. 512970-102699896
Bern, 22.05.2023

is to the best of my knowledge and ability, a faithful and accurate rendering of the original German text. The translation corresponds in all respects to the wording of the original.

bmp translations ag

John Purnell

Basel, June 9, 2023

LEGALISATION

We hereby certify that the signature of

BMP Translations AG

of Basel (Switzerland), which is known to us, is genuine, and that the person/s, who signed on its behalf, viz.

Purnell John translator

who is/are personally known to us, is/are authorized to sign jointly/individually.

No. **253518**

tax: **CHF 15.00**

Basel, **09.06.2023**

LEGALISATION OFFICE OF THE CANTON OF BASEL-CITY

Dominik Brodbeck

The certification refers exclusively to the signature and not the content or the authenticity of the signed document.

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