



**CERTIFICADO DE LIBERTAÇÃO DE LOTE**  
**BATCH RELEASE CERTIFICATE**

<b>Nome do Produto/Produç name</b>	<b>Somai Cannabisextrakt Hybrid 25:1 (THC:CBD)</b>
<b>ComposiçãoTHC:CBD/THC:CBD</b> <i>Composition</i>	<b>25:1 (THC:CBD)</b>
<b>Apresentação/Presentation</b>	<b>30 mL amber glass vials with screw cap</b>
<b>N.º de Lote/Batch Number</b>	<b>C0053</b>
<b>Nº de CoA/ CoA Number</b>	<b>nº2400917</b>
<b>Prazo de validade ou Prazo de reteste/Expire date or Retest date</b>	<b>31/01/2025</b>
<b>Quantidade/Quantity</b>	<b>300 units</b>
<b>Fabricado por Licença nº /</b> <i>Manufactured by authorization number</i>	<b>INFARMED authorization N° 42/V02 from 14/09/2023</b> <b>GMP Manufacture authorization number F081/001/2024 from 19/12/2023</b>
<b>Pais de destino/Destination country</b>	<b>Germany</b>
<b>Observações/Remarks</b>	<b>Not applicable</b>

**DECLARAÇÃO DE CERTIFICAÇÃO DE LIBERTAÇÃO**  
**RELEASE CERTIFICATION STATEMENT**

Certifico que a informação acima e anexa (CoA ) é autêntica e correta.  
Este lote foi fabricado, embalado e testado localmente em total cumprimento das Boas Práticas de Fabrico (BPFs) e dos requisitos da Autoridade Reguladora Local e de acordo com os termos descritos com **Canymed GmbH em acordo técnico de Qualidade de 26/02/2024**

*I certify that the enclosed and attached (CoA ) information is authentic and correct.  
This batch has been manufactured, packaged, and tested locally in full compliance with Good Manufacturing Practices (GMP's) and requirements of the Local Regulatory Authority and with the terms described in the Quality technical agreement with Canymed GmbH of 26/02/2024*

Carregado, 11 Março 2024  
Carregado, 11 th March , 2024

**Dália I.R.Gonçalves**  
*Direcção Técnica/Technical Director/Qualified Person*





## Certificate of Analysis

Specification	ESP-123/00
Product	Somai Cannabisextrakt Hybrid 25:1 (THC:CBD)
Code	FDF0012
Batch no.	C0053
Date of Analysis	08/03/2024

CoA no.	2400917
Manufacturing date	29/01/2024
Expiry date	31/01/2025
Presentation	30 mL amber glass vials with screw cap
Bulk batch no.	C0023

TEST	Method	Acceptance Criteria	Results
Appearance	MA-008	Slightly to yellowish liquid	Complies
Deliverable Volume	MA-008	Mean volume $\geq$ 30 mL; Individual volume $\geq$ 28.5 mL	Complies
Identification: HPLC	MA-008	The chromatograms of the sample solution obtained in the assay test must show the main peaks with a retention time similar to the chromatograms of the standard	Positive
Identification: TLC	MA-008	The sequence of zones in the chromatograms of the reference solution and the test solution are similar	Positive
Relative density	MA-008	Informative value	0.948
Water	MA-008	$\leq$ 0.5 %	0.06 %
<b>Cannabinoids</b>			
$\Delta^9$ -THC	MA-008 / DAB	Report value	25.21 mg/mL
$\Delta^9$ -THCA	MA-008 / DAB	Report value	< 0.003 (LOD) mg/mL
Total THC [THC+(THCAx0.877)]	MA-008 / DAB	90.0 % to 110.0 % of the label claim	100.8 % (25.21 mg/mL)
CBD	MA-008 / DAB	Report value	0.26 mg/mL
CBDA	MA-008 / DAB	Report value	< 0.003 (LOD) mg/mL
Total CBD [CBD+(CBDAx0.877)]	MA-008 / DAB	< 1.00 mg/mL	0.26 mg/mL
CBN	MA-008 / DAB	$\leq$ 1.0 %	0.03 %
Other cannabinoid (Together with any corresponding acid)	MA-008 / DAB	$\leq$ 2.0 %	0.13 %
Total other cannabinoids	MA-008 / DAB	Report value	0.47 %
<b>Mycotoxins</b>			
Aflatoxin B1	MA-008 / Ph.Eur.2.8.18	$\leq$ 2 $\mu$ g/Kg	< 0.25 (LOD) $\mu$ g/Kg
Aflatoxins (B1+B2+G1+G2)	MA-008 / Ph.Eur.2.8.18	$\leq$ 4 $\mu$ g/Kg	< 0.25 (LOD) $\mu$ g/Kg
Ochratoxin A	MA-008 / Ph.Eur.2.8.22	$\leq$ 20 $\mu$ g/Kg	< 2 (LOD) $\mu$ g/Kg
<b>Heavy Metals</b>			
Arsenic (As) *	Ph.Eur.2.4.27	$\leq$ 1.0 ppm	< 0.020 (LOQ) ppm
Cadmium (Cd) *	Ph.Eur.2.4.27	$\leq$ 0.5 ppm	< 0.005 (LOQ) ppm
Lead (Pb) *	Ph.Eur.2.4.27	$\leq$ 5.0 ppm	< 0.020 (LOQ) ppm
Mercury (Hg) *	Ph.Eur.2.4.27	$\leq$ 0.1 ppm	< 0.050 (LOQ) ppm
Nickel (Ni) *	Ph.Eur.2.4.27	Indicative	< 2.000 (LOQ) ppm
Zinc (Zn) *	Ph.Eur.2.4.27	Indicative	< 3.996 (LOQ) ppm



## Certificate of Analysis

Specification	ESP-123/00
Product	Somai Cannabisextrakt Hybrid 25:1 (THC:CBD)
Code	FDF0012
Batch no.	C0053
Date of Analysis	08/03/2024

CoA no.	2400917
Manufacturing date	29/01/2024
Expiry date	31/01/2025
Presentation	30 mL amber glass vials with screw cap
Bulk batch no.	C0023

TEST	Method	Acceptance Criteria	Results
<b>Pesticides</b>			
Pesticides *	Ph.Eur.2.8.13	Complies with Ph.Eur.2.8.13	Complies
<b>Residual solvents</b>			
Ethanol *	Ph.Eur.5.4	< 5000 ppm	< 2228.5 (LOQ) ppm
<b>Microbial Quality</b>			
TAMC - Total aerobic microbial count	MA-008 / Ph.Eur.2.6.12. & Ph.Eur.5.1.4.	$\leq 10^3$ CFU/mL	< 10 CFU/mL
TYMC - Total combined yeast & mould count	MA-008 / Ph.Eur.2.6.12. & Ph.Eur.5.1.4.	$\leq 10^2$ CFU/mL	< 10 CFU/mL
Bile-tolerant gram-negative bacteria	MA-008 / Ph.Eur.2.6.13 & Ph. Eur. 5.1.4.	$\leq 10^2$ CFU/mL	< 10 CFU/mL
<i>Escherichia coli</i>	MA-008 / Ph.Eur.2.6.13 & Ph. Eur. 5.1.4.	Absence in 1 mL	Absence/mL
<i>Salmonella</i>	MA-008 / Ph.Eur.2.6.13 & Ph. Eur. 5.1.4.	Absence in 10 mL	Absence/10mL
<i>Staphylococcus aureus</i>	MA-008 / Ph.Eur.2.6.13 & Ph. Eur. 5.1.4.	Absence in 1 mL	Absence/mL

### Comments

Results in compliance with the specification.

Mycotoxins, Heavy Metals, Pesticides and Ethanol were performed on the purified extract batch.

(\*)Result reported from LEF (CoA 23/5477)

### Approved By:

Iva Vinhas

Quality Control Director

11/03/2024 14:16

*Application of electronic signature*