Reference Specification Legacy number: F-COA-009-DE

Batch Details			
Batch number -Bulk oil	25/014-MT	**Manufacturing date**	01/2025
Batch number - Finish product	25/037-MT	**Expiry date**	01/2027

Test	Test Method	Specifications	Result
Identification			
TLC identification	SOP QC-179-MT/ VA1112 *DAB* £	Zonal pattern of test solution conforms to the zonal pattern of the reference solution	Complies
Organoleptic properties			
Appearance	SOP QC-136-MT Visual inspection *DAB* £	Homogenous greenish or yellow to brown liquid, no significant precipitate observed	Complies
Heavy metals[1,2]			
Cadmium	SOP 77405 ICP-MS *Ph. Eur. 2.4.27* ◊	≤ 1.0 ppm	< 0.05 ppm
Lead		≤ 5.0 ppm	< 0.1 ppm
Mercury		≤ 0.1 ppm	< 0.05 ppm
Physico-chemicals			
Relative density	SOP-183-MT / VA1044 *Ph. Eur. 2.2.5* ◊	Indicative	0.95
Water content	SOP-175-MT/ VA25322 Karl Fisher *Ph. Eur. 2.5.12* ◊	≤0.5%	< 0.2%
Toxins- Mycotoxins			
Aflatoxin B1	SOP QC-131-MT /VA45110 *Ph. Eur. 2.8.18* ◊	≤ 2 µg/Kg	< LOQ
Total Aflatoxins (B1, B2, G1, G2)		≤ 4 µg/Kg	< LOQ
Microbiological Quality [1]			
TAMC	MW024-01 *Complies to Ph. Eur. 2.6.12* ◊	≤ 10^4 CFU/ml	<100 CFU/ml
TYMC		≤ 10^2 CFU/mL	<10 CFU/ml
Bile-tolerant gram-negative bacteria	MW024-01 *Complies to Ph. Eur 2.6.31* ◊	< 10^2 CFU/ml	<10 CFU/ml
E.Coli		Absent in 1ml	Absent in 1 ml
Salmonella		Absent in 25 ml	Absent in 25 ml
Residual solvent			
Ethanol	QC-140-MT/ VA12301 GC-HS-FID	≤ 5000 ppm	NA
Assay - Cannabinoids concentration (%w/w)			
CBN	QC-181-MT *DAB* £	≤ 2.5% m/m	0.0%
CBD		2.47% - 2.73% m/m (95-105 % from label claim)	2.61%
Δ9-THC		≤ 0.16% m/m (≤ 6% from CBD label claim)	0.11%
Vitamin E	QC-149-MT / VA14060	≥ 0.4% m/m	0.5%

Pesticide Residue [1,2]			
Pesticides	SOP 15005, 15010 LC-MS/MS, GC-MS/MS, Headspace-GC/MS *Ph. Eur.2.8.13* ◊	*Complies with the limits indicated in Ph. Eur.2.8.13*	Complies

Aflatoxins UQL- Under quantification limit; LOQ Aflatoxin B1, B2, G1: 0,5 µg/kg; LOQ Aflatoxin G2: 1,0 µg/kg.
Residual Solvents UDL – Under detection limit. The result of Ethanol that is less than 170ppm is reported UDL.
Residual Solvents UQL – Under quantification limit. The result of Ethanol that is less than 500ppm is reported UQL.
Assay URL – Under reporting level. The concentration of THC and CBN that are less than 0.05% from the label amount of CBD are reported URL (0.001%)
◊ Current version of monograph
£ DAB *Cannabis extractum normatum* monograph
1. Performed by approved outsource laboratory
2. Pesticides and Heavy metals – To be performed every 20th Batch. When skip lot testing is performed both results are reported from the Inflorescence COA.
3. Residual solvent - To be performed every 20th Batch.

Consecutive batch number:	***Pesticides and Heavy metals testing required on Finished product:***
2	☐ Yes; ☒ No, results reported from Inflorescence COA/s. Batch no./s used during manufacturing: 24/173-MT

☒ PASS ☐ FAIL

QC Reviewed by:	**Signature:**	**Date:**
Chris Desira		February 24, 2025

Following the review of the manufacturer's COA and in-house testing, the batch concerned is considered meeting/not meeting Panaxia's Specifications and requirement, hence this batch is: ☐ **Approved/** ☐ **Rejected.**

Approved by:	**Signature:**	**Date:**
Shani Bonan		February 24, 2025

REVISION HISTORY				
Date	**Name of corrector**	**Version no**	**Details of correction (including Chapter No)**	**Reason of correction**
12.03.2024	Shani Bonan	01	New Document	CCF-MT-2024-23
28/10/2024	Shani Bonan	02	1. Adding the method's number of QSI 2. Adding Residual solvent - To be performed every 20th Batch	1. CC-0000022 2. CC-0000016
11/02/2025	Shani Bonan	03	Remove Ochratoxin test	CC-0000033

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signatures.

Signatory Table

Action Name	User Name	Title	Signature Date
Send for Review (Written By)	Shani Bonan	QC Manager	13-Feb-2025 08:36
Review	Chris Desira	Head of Quality Assurance	18-Feb-2025 14:09
Send for Approval	Chris Desira	Head of Quality Assurance	18-Feb-2025 14:10
Approve	Shani Bonan	QC Manager	18-Feb-2025 14:57
QA Approval	Irene Zanetti	Qualified Person	21-Feb-2025 08:41
Approve	Irene Zanetti	Qualified Person	21-Feb-2025 08:41

* Dates are displayed according to the system time zone: (GMT+01:00) Central European Standard Time (Europe/Malta)

Reference Specification Legacy number: F-SPC-009-MT

Panaxia Malta Batch No:	PRT Number:	Expiry Date:
25/014-MT	WP-000014-MT	01/2027

1. Specifications:

Test	Test Method	Specifications	Result
Identification [1]			
TLC identification	SOP QC-179-MT/ VA1112 *DAB* £	Zonal pattern of test solution conforms to the zonal pattern of the reference solution	Complies
Organoleptic properties			
Appearance	SOP QC-136-MT Visual inspection *DAB* £	Homogenous greenish or yellow to brown liquid, no significant precipitate observed	Complies
Physico-chemicals[1]			
Relative density	SOP-183-MT / VA1044 *Ph. Eur. 2.2.5* ◊	Indicative	0.95
Water content	SOP-175-MT/ VA25322 Karl Fisher *Ph. Eur. 2.5.12* ◊	≤0.5%	<0.2%
Heavy metals[1,2]			
Cadmium	SOP 77405 ICP-MS *Ph. Eur. 2.4.27* ◊	≤ 1.0 ppm	< 0.05 ppm
Lead		≤ 5.0 ppm	< 0.1 ppm
Mercury		≤ 0.1 ppm	< 0.05 ppm
Toxins- Mycotoxins[1]			
Aflatoxin B1	SOP QC-131-MT/ VA45110 *Ph. Eur. 2.8.18* ◊	≤ 2 µg/Kg	< LOQ
Total Aflatoxins (B1, B2, G1, G2)		≤ 4 µg/Kg	< LOQ
Microbiological Quality [1]			
TAMC	MW024-01/*VA52090* *Complies to Ph. Eur. 2.6.12* ◊	≤ 10^4 CFU/mL	< 100 CFU/ml
TYMC		≤ 10^2 CFU/mL	<10 CFU/ml
Bile-tolerant gram-negative bacteria	MW024-01/ *VA52090* *Complies to Ph. Eur 2.6.31* ◊	< 10^2 CFU/mL	<10 CFU/ml
E.Coli		Absent in 1 mL	Absent in 1 ml
Salmonella		Absent in 25 mL	Absent in 25 ml
Residual solvent [3]			
Ethanol	QC-140-MT/VA12301 GC-HS-FID	≤ 5000 ppm	NA
Assay			
CBN	QC-181-MT *DAB* £	≤ 2.5% m/m	0.0%
CBD		2.47% - 2.73% m/m (95-105 % from label claim)	2.61%
Δ9-THC		≤ 0.16% m/m (≤ 6% from CBD label claim)	0.11%
Vitamin E[1]	QC-149-MT / VA14060	≥ 0.4% m/m	0.5%

Pesticide Residue [1,2]			
Pesticides	SOP 15005, 15010 LC-MS/MS, GC-MS/MS, Headspace-GC/MS *Ph. Eur.2.8.13* ◊	*Complies with the limits indicated in Ph. Eur.2.8.13*	Complies

Aflatoxins UQL- Under quantification limit; LOQ Aflatoxin B1, B2, G1: 0,5 µg/kg; LOQ Aflatoxin G2: 1,0 µg/kg.
Residual Solvents UDL – Under detection limit. The result of Ethanol that is less than 170ppm is reported UDL.
Residual Solvents UQL – Under quantification limit. The result of Ethanol that is less than 500ppm is reported UQL.
Assay URL – Under reporting level. The concentration of THC and CBN that are less than 0.05% from the label amount of CBD are reported URL (0.001%)
◊ Current version of monograph
£ DAB *Cannabis extractum normatum* monograph
1. Performed by approved outsource laboratory.
2. Pesticides and Heavy metals – To be performed every 20th Batch. When skip lot testing is performed both results are reported from the Inflorescence COA.
3.Residual solvent - To be performed every 20th Batch.

Consecutive batch number:	***Pesticides and Heavy metals testing required on Finished product:***
2	☐ Yes; ☒ No, results reported from Inflorescence COA/s. Batch no./s used during manufacturing: 24/173-MT

2. Packaging:
30 mL of Standardized Extract filled in a 30 mL amber glass pharma grade bottle (PK-000007-MT) with:
2.1. ☐ **Child Resistant Caps (WP-000045-MT):** a screw cap tamper evident and child safety lock (PK-000013-MT).
2.2. ☒ **Non-Child Resistant Caps (WP-000014-MT):** a screw cap tamper evident (PK-000008-MT).

3. Shelf life: 24 months
4. Storage conditions: Store in a cool, dry place, protected from light and at a temperature not exceeding 25°C.

☒ **PASS** ☐ **FAIL**		
Analysed by: Chris Desira	**Signature:**	**Date:** February 24, 2025
Following the review of the manufacturer's COA and in-house testing, the batch concerned is considered meeting/not meeting Panaxia's Specifications and requirement, hence this batch is: ☒ **Approved/** ☐ **Rejected.**		
QC approved by: Shani Bonan	**Signature:**	**Date:** February 24, 2025

REVISION HISTORY				
Date	**Name of corrector**	**Version no**	**Details of correction (including Chapter No)**	**Reason of correction**
12/03/2024	Shani Bonan	01	New Document	CCF-MT-2024-23
28/10/2024	Shani Bonan	02	1. Adding the method's number of QSI 2. Adding Residual solvent - To be performed every 20th Batch.	1. CC-0000022 2. CC-0000016
11/02/2025	Shani Bonan	03	Remove Ochratoxin test	CC-0000033

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signatures.

Signatory Table

Action Name	User Name	Title	Signature Date
Send for Review (Written By)	Shani Bonan	QC Manager	13-Feb-2025 08:18
Review	Chris Desira	Head of Quality Assurance	18-Feb-2025 14:02
Send for Approval	Chris Desira	Head of Quality Assurance	18-Feb-2025 14:11
Approve	Chris Desira	Head of Quality Assurance	18-Feb-2025 14:12
Approve	Shani Bonan	QC Manager	18-Feb-2025 14:57
Approve	Irene Zanetti	Qualified Person	21-Feb-2025 08:40
QA Approval	Irene Zanetti	Qualified Person	21-Feb-2025 08:41

* Dates are displayed according to the system time zone: (GMT+01:00) Central European Standard Time (Europe/Malta)

24/098-MT

SGD S.A.
Simplified joint stock company with capital of 44 081 866 Euros - Nanterre Trade and Companies Register N°B552 012 585 - VAT I/D : FR 29 552 012 585
Head Office and Sales Departements : Tour Liberty - 17 place des Reflets - 92097 Paris La Défense Cédex - France. Phone:+33(0)1 40 90 36 00 - Fax:+33(0)1 40 90 36 01
Postal address : Tour Liberty - 17 place des Reflets - CS 30300 - 92097 Paris La Défense Cédex - France

CERTIFICATE OF QUALITY

The 30.09.2024

Customer PANAXIA PHARMACEUTICAL MALTA / 39810
BBG3000 ESTATE BIRZEBBUGA MT

Delivery adress PANAXIA PHARMACEUTICAL MALTA / 39810001
BBG3000 ESTATE BIRZEBBUGA MT

Customer's order	PO24000326	**from** 27.08.2024	
Customer's product code	GI000201-MT		
Delivery	81563419	**Quantity Delivered**	19.404 PCE
SGD Product Code	02543 07 020	TROPFFL. 30 ML	
SGD Drawing N	69676I	Type III AMBER GLASS	
Treatment	None		
Run Number	N 241345	**Manufacturing Date**	14.06.2024 to 26.06.2024
Quantity per Pallet	9.702	**Production Site**	SUCY EN BRIE France

Glass quality

	Unit	Specifications		Results			
		Min	Max	Min	Max	Ave	S-D
ARSENIC	ppm	N/A	0,100	0,001	0,001	0,001	0,000
Hydro-resist-powder/1g	ml	N/A	0,850	0,520	0,520	0,520	0,000
Hydrolytic resistance (HCl)	ml	N/A	6,100	5,500	5,740	5,640	0,120
Spectral transmission	%	N/A	10,000	0,940	0,940	0,940	0,000
Annealing	N/A	N/A	18,000	Conforms			

Glass measurements

	Unit	Specifications		Results			
		Min	Max	Min	Max	Ave	S-D
Body diameter	mm	31,900	32,900	32,120	32,310	32,224	0,032
Mini Internal bore	mm	9,500	N/A	11,000	11,730	11,376	0,160
Neck finish height 2	mm	10,800	11,200	10,970	11,090	11,015	0,031
Maxi External neck	mm	N/A	18,000	17,690	17,950	17,780	0,058
Minor thread diameter	mm	15,680	15,980	15,790	15,900	15,855	0,025
Opening diameter	mm	10,450	10,750	10,600	10,750	10,698	0,037
Total height	mm	78,500	80,100	79,170	79,570	79,417	0,099
Neck finish diameter	mm	17,700	18,000	17,730	17,880	17,810	0,036
Bead diameter	mm	19,800	20,200	19,840	20,050	19,989	0,044
Neck finish height	mm	13,500	13,900	13,500	13,620	13,570	0,025

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SGD S.A.
Simplified joint stock company with capital of 44 081 866 Euros - Nanterre Trade and Companies Register N°B552 012 585 - VAT I/D : FR 29 552 012 585
Head Office and Sales Departements : Tour Liberty - 17 place des Reflets - 92097 Paris La Défense Cédex - France. Phone:+33(0)1 40 90 36 00 - Fax:+33(0)1 40 90 36 01
Postal address : Tour Liberty - 17 place des Reflets - CS 30300 - 92097 Paris La Défense Cédex - France

CERTIFICATE OF QUALITY

The 30.09.2024

Customer PANAXIA PHARMACEUTICAL MALTA / 39810
BBG3000 ESTATE BIRZEBBUGA MT

Delivery adress PANAXIA PHARMACEUTICAL MALTA / 39810001
BBG3000 ESTATE BIRZEBBUGA MT

Customer's order	PO24000326	**from** 27.08.2024	
Customer's product code	GI000201-MT		
Delivery.	81563419	**Quantity Delivered**	19.404 PCE
SGD Product Code	02543 07 020	TROPFFL. 30 ML	
SGD Drawing N	69676I	Type III AMBER GLASS	
Treatment	None		
Run Number	N 241345	**Manufacturing Date** 14.06.2024 **to**	26.06.2024
Quantity per Pallet	9.702	**Production Site** SUCY EN BRIE	France

We, SGD S.A., hereby certify that the above referred bottles have been tested and are in conformity with :

THE SPECIFICATIONS IN FORCE

TO THE CURRENT ISO 15378 VERSION

THE HYDROLYTIC RESISTANCE

- To the requirements of the European Pharmacopoeia in force
- To the requirements of the USP in force
- Hydrolytic Resistance testing - Grain - is done at least once per year.

ARSENIC

- To the requirements of the European Pharmacopoeia in force
- To the requirements of the USP in force
- Arsenic tests are carried out once per year by Furnace

SPECTRAL TRANSMISSION

- To the requirements of the European Pharmacopoeia in force
- To the requirements of the USP in force

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SGD S.A.
Simplified joint stock company with capital of 44 081 866 Euros - Nanterre Trade and Companies Register N°B552 012 585 - VAT I/D : FR 29 552 012 585
Head Office and Sales Departements : Tour Liberty - 17 place des Reflets - 92097 Paris La Défense Cédex - France. Phone:+33(0)1 40 90 36 00 - Fax:+33(0)1 40 90 36 01
Postal address : Tour Liberty - 17 place des Reflets - CS 30300 - 92097 Paris La Défense Cédex - France

CERTIFICATE OF QUALITY

The 30.09.2024

Customer PANAXIA PHARMACEUTICAL MALTA / 39810
BBG3000 ESTATE BIRZEBBUGA MT

Delivery adress PANAXIA PHARMACEUTICAL MALTA / 39810001
BBG3000 ESTATE BIRZEBBUGA MT

Customer's order	PO24000326	**from** 27.08.2024	
Customer's product code	GI000201-MT		
Delivery	81563419	**Quantity Delivered**	19.404 PCE
SGD Product Code	02543 07 020	TROPFFL. 30 ML	
SGD Drawing N	69676I	Type III AMBER GLASS	
Treatment	None		
Run Number	N 241345	**Manufacturing Date**	14.06.2024 to 26.06.2024
Quantity per Pallet	9.702	**Production Site**	SUCY EN BRIE France

Glass characteristics

	Unit	Specifications		Results			
		Min	Max	Min	Max	Ave	S-D
Weight	g	N/A	N/A	40,000	41,600	40,926	0,410
Capacity	ml	34,300	36,700	34,900	35,800	35,417	0,189
Vertical load	kg/cm	200,000	N/A	400,000	400,000	400,000	0,000
Thermal shock	kg/cm	200,000	400,000	Conforms			

Quality Manager
Aline BAILLET

PANAXIA Pharmaceutical Industries

Panaxia Pharmaceutical Malta (Operations) Ltd.
HHF001A Hal Far, B'Buga BBG 3000, Malta

Document title	Document type	Document No.	Version
COA for Herbal Substance as raw material for oil (Rich CBD) – Not Dried Flower	**Specification**	**F-SPC-012-MT**	**02**
Effective date: 30/05/2024		Page 1 of 3	

Manuf. Batch No: GCA2411B1	**Panaxia Malta Batch No:** 24l173-MT **(Wet flower Batch No. if applicable:** N/A **)**
PRT NUMBER: RM-000030-MT	**Re-test date (to be determined after testing):** 28/09/2024

1. Specifications:

Test	Test Method*	Specifications	Result
Identification and other tests			
Macroscopic[2]	*SOP QC-129-MT* *Complies to Ph. Eur 1433*	Brown to green Shredded/clustered inflorescence with characteristic smell with no visual molds ,external pests, stalks or foreign objects	Complies
Microscopic[2]	*SOP QC-130-MT* *Complies to Ph. Eur 2.8.23*	Features comply	Complies
TLC [2]	*SOP QC-132-MT* *Complies to Ph. Eur 2.2.27*	Zonal pattern complies	Complies
HPLC PDA-UV spectrum identification[3]	*SOP QC-145-MT*	Complies to standards spectrum	Complies
Foreign matter	*SOP QC-111-MT* *Complies to Ph. Eur EP 2.8.2*	≤ 2%	0%
Water Determination	*SOP QC-134-MT* *Complies to Ph. Eur 2.5.12*	≤ 20%	6%
Pesticide residues- Performed by approved outsource laboratory			
Pesticides	*SOP 15000/ SOP 15010* *Complies to Ph. Eur 2.8.13,*	Comply with the permitted levels for pesticides	Complis
Heavy metals- Performed by approved outsource laboratory			
Arsenic	*SOP 77400* *Complies to Ph. Eur 2.4.27*	≤ 0.2 ppm	<0.1ppm
Cadmium		≤ 1.0 ppm	<0.05ppm
Lead		≤ 5.0 ppm	<0.1ppm
Mercury		≤ 0.1 ppm	<0.05ppm
Toxins- Mycotoxins			
Aflatoxin B1	*SOP QC-131-MT* *Complies to Ph. Eur 2.8.18*	≤ 2 µg/Kg	ND
Total Aflatoxins (B1,B2.G1,G2)		≤ 4 µg/Kg	ND
Ochratoxin A	SOP QC-322-MT HPLC *Ph. Eur 2.8.22*	≤ 30.4 µg/Kg	UDL

AUTHORIZATION				QA Authorized Stamp
ISSUED BY:	QC APPROVED BY:	QA APPROVED BY:	RA APPROVED BY:	
INITIALS AND DATE:	INITIALS AND DATE:	INITIALS AND DATE:	INITIALS AND DATE:	
May 23, 2024	May 23, 2024	May 29, 2024	May 29, 2024	

Microbial contamination - Performed by approved outsource laboratory			
TAMC	VA52105 *Complies to Ph. Eur 2.6.12-2.6.13*	≤ 10^7 CFU/g	<100,000 cfu/g
TYMC		≤ 10^5 CFU/g	<10,000 cfu/g
E. Coli		10^3 (CFU/ g)	<10 cfu/g
Salmonella		Absence (25g)	Absent in 25g
Active Ingredients			
CBDA	*QC-107-MT, QC-133-MT*	Indicative (%)	4.95%
CBGA		Indicative (%)	0.16%
CBD		Indicative (%)	1.49%
CBG		Indicative (%)	UQL
THCV		Indicative (%)	UQL
CBN		≤ 1.0%	0.0% (UQL)
Δ^9 THC		Indicative (%)	0.24%
Δ^8 THC		Indicative (%)	UQL
CBC		Indicative (%)	0.16%
THCA		Indicative (%)	0.21%
Total Δ^9 THC equivalents	*%THC + 0.877*%THCA*	≤ 1.0%	0.4%
Total CBD equivalents	*%CBD + 0.877*%CBDA*	≥5%	9%
Total CBG equivalents	*%CBG + 0.877*%CBGA*	Indicative (%)	0.2%
Total CBD equivalents: Total Δ^9 THC equivalents	*Ratio*	≥20:1	23
Total CBD equivalents+ Total Δ^9 THC equivalents	*Sum*	≥5%	9%

1. ***UQL*** - under quantification limit (UQL<0.055% $^{\Delta 9}$THC, THCA, CBD, CBDA, CBG, CBGA, and <0.011% for CBN and CBC).
2. ***Microscopic/Macroscopic/TLC*** – Identity testing should be carried out on all containers.
3. ***HPLC PDA-UV spectrum identification***– Identity testing should be carried out on Bulk sample.

AUTHORIZATION				QA Authorized Stamp
ISSUED BY:	QC APPROVED BY:	QA APPROVED BY:	RA APPROVED BY:	
INITIALS AND DATE:	INITIALS AND DATE:	INITIALS AND DATE:	INITIALS AND DATE:	
May 23, 2024	May 23, 2024	May 29, 2024	May 29, 2024	

2. Packaging and Labeling

2.1 Each package must be labeled, by Seach with at least the following information:

2.1.1 Product Name
2.1.2 Manufacturer Batch number
2.1.3 Net weight
2.1.4 Re-test date: Refer to QA-259-MT

3. Storage conditions:

3.1 Store in a cool, dry place at a temperature not exceeding 25°C.

Documented by:	Signature:	Date:
Maria Agius		17 OCT 2024

☐ **Version 01:** **Temporary release:** All in-house Testing performed except for Aflatoxins, Ochratoxins, Pesticides and Heavy metals (In-process).

☑ **Version 02:** **Approved:** All in-house and outsourced testing performed.

☐ **Version 03** ☐ **N/A** : **Re-test no.** NA : All in-house re-test testing performed as per QC-259-MT.

QC approved by:	Signature:	Date:
Chris Zerafa		17 OCT 2024

REVISION HISTORY

Date	Name of corrector	Version no	Details of correction (including Chapter No)	Reason of correction
02/04/2024	Shani Bonan	01	New Document	CCF-MT-2024-23
13/05/2024	Maria Agius	02	Updated temporary approval section to allow for this type of approval prior to sending the samples for external testing.	Final version will include external testing.

AUTHORIZATION				QA Authorized Stamp
ISSUED BY:	QC APPROVED BY:	QA APPROVED BY:	RA APPROVED BY:	
INITIALS AND DATE:	INITIALS AND DATE:	INITIALS AND DATE:	INITIALS AND DATE:	
May 23, 2024	May 23, 2024	May 29, 2024	May 29, 2024	

Manuf. Batch No: GCA2411B1	Panaxia Malta Batch No: 24/173-MT -2M
PRT NUMBER: RM-000030-MT	Re-test date (to be determined after testing): 28/11/2024

1. Specifications:

Test	Test Method*	Specifications	Result
Identification and other tests			
Loss on Dry	*VA25858* *Complies to Ph. Eur 2028*	≤ 20%	8%
Toxins- Mycotoxins			
Aflatoxin B1	*SOP QC-131-MT VA45110* *Complies to Ph. Eur 2.8.18*	≤ 2 µg Kg	UQL
Total Aflatoxins (B1,B2,G1,G2)		≤ 4 µg Kg	UQL
Ochratoxin A	SOP QC-322-MT VA45118 *Ph. Eur 2.8.22*	≤ 30.4 µg Kg	UQL
Microbial contamination - Performed by approved outsource laboratory			
TAMC	VA52105 *Complies to Ph. Eur 2.6.12-2.6.13*	≤ 10^7 CFU/g	350000
TYMC		≤ 10^5 CFU/g	25000
E. Coli		10^3 (CFU/g)	<10 CFU/ml
Salmonella		Absence (25g)	Absent in 25 g
Active Ingredients			
CBDA	*VA31991* *Complies to Ph. Eur 2028*	Indicative (%)	8.1%
CBGA		Indicative (%)	0.1%
CBD		Indicative (%)	2.5%
CBG		Indicative (%)	<0.1%
THCV		Indicative (%)	<0.1%
CBN		≤ 1.0%	<0.1%
Δ^9 THC		Indicative (%)	0.2%
CBC		Indicative (%)	<0.1%
THCA		Indicative (%)	0.2%
Total Δ^9 THC equivalents	*%THC + 0.877*%THCA*	Indicative (%)	0.4%
Total CBD equivalents	*%CBD + 0.877*%CBDA*	90%-110% related to T0 T0 Assay: 8 %(i.e 10 % to %)	10%
Total CBG equivalents	*%CBG + 0.877*%CBGA*	Indicative (%)	0.1%
Total CBD equivalents: Total Δ^9 THC equivalents	*Ratio*	≥20:1	25
Total CBD equivalents– Total Δ^9 THC equivalents	*Sum*	≥6%	10%

1. *UQL* - under quantification limit (UQL=0.055% ^{9}THC, THCA, CBD, CBDA, CBG, CBGA, and <0.01% for CBN and CBC).

2. **Packaging and Labeling**

2.1 Each package must be labeled, by Seach with at least the following information:

2.1.1 Product Name

2.1.2 Manufacturer Batch number

2.1.3 Net weight

2.1.4 Re-test date: TBD

3. **Storage conditions:**

3.1 Store in a cool, dry place at a temperature not exceeding 25°C.

Documented by: Shani Bonan	**Signature:**	**Date:** December 9, 2024
QC approved by: Chris Desira	**Signature:**	**Date:** December 9, 2024

REVISION HISTORY				
Date	**Name of corrector**	**Version no**	**Details of correction (including Chapter No)**	**Reason of correction**
30/09/2024	Maria Agius	01	New Document	PAN-0534
10/10/2024	Shani Bonan	02	change specification of CBDA from 90-110% to indicative.	Acidic forms degrade to CBD over time.
09/12/2024	Shani Bonan	03	1. Adding the method's number of QSI 2. Change KF to LOD	1. CC-0000022 2. *Complies to Ph. Eur 3025*

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signatures.

Signatory Table

Action Name	User Name	Title	Signature Date
Send for Review (Written By)	Shani Bonan	QC Manager	09-Dec-2024 14:31
Review	Chris Desira	Head of Quality Assurance	09-Dec-2024 14:52
Send for Approval	Chris Desira	Head of Quality Assurance	09-Dec-2024 14:53
Approve	Chris Desira	Head of Quality Assurance	09-Dec-2024 14:54
Approve	Shani Bonan	QC Manager	09-Dec-2024 15:19
Approve	Ivan Vidmar	Senior QA Specialist	09-Dec-2024 15:43
QA Approval	Ivan Vidmar	Senior QA Specialist	09-Dec-2024 15:44

* Dates are displayed according to the system time zone: (GMT+01:00) Central European Standard Time (Europe/Malta)

Certificate of Conformity

Call: +44 (0) 1482 638380
Melton House Wyke Way Melton
East Yorkshire HU14 3HJ

Email: info@originltd.com
www.originltd.com

Invoice To:

Panaxia Pharmaceutical Malta (Operations) LTD
HHF001A Ħal Far
Birżebbuġa
MALTA
MT26344313

Account Ref:	PANA003
Certificate No	**115312 v1**
Customer Order No	PO23000457
Date	22/05/2024

Product Code	Product Description	No of Cases	Unit Qty	Qty Despatched
OS1W3-W	1ml White Oral Dosage Syringe - 0.01ml Graduations - Wrapped	20,000.00	1.00	20,000
Your Prod Code:	PK000221-MT			

Batch Info:

#	Batch	Quantity	Manufacturer Batch Ref
1	P0057883	20,000	BRV240313

OS1W3-W	1ml White Oral Dosage Syringe - 0.01ml Graduations - Wrapped (V4.9)	30,000.00	1.00	30,000
Your Prod Code:	PK000221-MT			

Batch Info:

#	Batch	Quantity	Manufacturer Batch Ref
1	P0057883	30,000	BRV240313

Deliver To:

Panaxia Pharmaceutical Malt
HHF001A Ħal Far
Birżebbuġa
MALTA

Certificate of Conformity

We confirm that the products detailed herein have been supplied from a QA approved source and have been manufactured, inspected and tested in accordance with the manufacturers

BHARAT RUBBER WORKS
Healthcare Packaging Solutions

CERTIFICATE OF ANALYSIS

Product: 1ml Dosing Syringe
Product Code: SYPN01-WH - CE
Batch/Lot No.: BRV240313
A.R. No.: FG-24-0698
MFG Date: 08/05/2024

Date: 13/05/2024
Batch/Lot size: 30,000 NOS
Challan No.: EXP/4/2024-25
Exp Date: 3 Years from MFG.

Party's Name: Origin Packaging Ltd.

Sr. No.	Tests	Specification	Results
A	Description	1ml Dosing syringe marked at volume of 0.05ml, 0.06ml, 0.07ml, 0.08ml, 0.09ml.... up to 1ml with instruction (FOR ORAL USE ONLY) with individual BOPP sealing and CE0123 mark.	Complies
B	Appearance	Should confirm with	Complies
		(I) Colour Barrel: Natural (Markings in Black Ink) Plunger: WHITE (PL00075542)	
		(II) Clarity	
		(III) Free from embedded foreign particles and dust particles.	
		(IV) Free from cuts & Un filings.	
C	Physical Test		
(a)	Syringe Barrel		
1	Material	Polypropylene	Complies
2	Grade	RP375R	Complies
3	Total Height	86.50 mm ± 1.0 mm	85.79 mm - 85.80 mm
4	Outer Diameter	6.50 mm ± 0.3 mm	6.43 mm - 6.58 mm
5	Inner Dimeter At Tip	2.40 mm ± 0.2 mm	2.24 mm - 2.42 mm
6	Outer Dimeter At Tip	5.10 mm ± 0.2 mm	4.95 mm - 5.10 mm
7	Flange Diameter	18.50 mm ± 0.3 mm	18.46 mm - 18.65 mm
8	Volume Marking	0.05ml, 0.06ml, 0.07ml, 0.08ml, 0.09ml, 0.1ml.... up to 1ml ± 10 %	Complies
(b)	Syringe Plunger		
1	Material	High Density Polyethylene	Complies
2	Grade	ACP 6541A	Complies
3	Total Height	92.50 mm ± 1.0 mm	92.38 mm - 92.65 mm
4	Sucking Od	4.85 mm ± 0.2 mm	4.83 mm - 4.97 mm
5	Collar Diameter	15.00 mm ± 0.3 mm	15.05 mm - 15.19 mm
(c)	Pouch		
1	Length Of Pouch	130.00 mm ± 10.0 mm	125 mm - 138 mm
2	Width Of Pouch	30.00 mm ± 5.0 mm	28 mm - 33 mm

Complies with our specification No. -BRV/FG-1903

Analyzed by: 13/05/2024

Approved by: for 13/05/2024

Format No. FQC/021-06/00

ADDRESS: PLOT NO.15-16, S. NO. 66, NAIKPADA SAI PRABHAT UDYOG NAGAR-2 WALIV VASAI, PALGHAR, MAHARASHTRA 401208

BHARAT RUBBER WORKS
Healthcare Packaging Solutions

CERTIFICATE OF ANALYSIS

Product: 1ml Dosing Syringe
Product Code: SYPN01-WH - CE
Batch/Lot No.: BRV240313
A.R. No.: FG-24-0698
MFG Date: 08/05/2024

Date: 10/05/2024
Batch/Lot size: 20,000 NOS
Challan No.: EXP/2/2024-25
Exp Date: 3 Years from MFG.

Party's Name: Origin Packaging Ltd.

Sr. No.	Tests	Specification	Results
A	Description	1ml Dosing syringe marked at volume of 0.05ml, 0.06ml, 0.07ml, 0.08ml, 0.09ml.... up to 1ml with instruction (FOR ORAL USE ONLY) with individual BOPP sealing and CE0123 mark.	Complies
B	Appearance	Should confirm with	Complies
		(I) Colour Barrel: Natural (Markings in Black Ink) Plunger: WHITE (PL00075542)	
		(II) Clarity	
		(III) Free from embedded foreign particles and dust particles.	
		(IV) Free from cuts & Un filings.	
C	Physical Test		
(a)	Syringe Barrel		
1	Material	Polypropylene	Complies
2	Grade	RP375R	Complies
3	Total Height	86.50 mm ± 1.0 mm	85.79 mm - 85.80 mm
4	Outer Diameter	6.50 mm ± 0.3 mm	6.43 mm - 6.58 mm
5	Inner Dimeter At Tip	2.40 mm ± 0.2 mm	2.24 mm - 2.42 mm
6	Outer Dimeter At Tip	5.10 mm ± 0.2 mm	4.95 mm - 5.10 mm
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5	Collar Diameter	15.00 mm ± 0.3 mm	15.05 mm - 15.19 mm
(c)	Pouch		
1	Length Of Pouch	130.00 mm ± 10.0 mm	125 mm - 138 mm
2	Width Of Pouch	30.00 mm ± 5.0 mm	28 mm - 33 mm

Complies with our specification No. -BRV/FG-1903

Analyzed by: NShah 10/05/2024

Approved by: 10/05/2024

Format No. FQC/021-06/00

COMPANY / *UNTERNEHMEN*:
DATE / *DATUM*: 14/12/23

Remy & Geiser GmbH
Ein Unternehmen der Bormioli Pharma Group
Sitz: Remy & Geiser Straße 1 98553 Schleusingen (OT Hintermah), Germany

DECLARATION OF CONFORMITY	*KONFORMITÄTSERKLÄRUNG*

ARTICLE / *Art.-Code*	8840MA-AR240001
DELIVERY NOTE / *Lieferschein Nr*	23004312
CUSTOMER ARTICLE ID / *Kunde Art.-Code*	
DESCRIPTION / *Art.-Bez.*	KINDERGESICHERTER VERSCHLUSS KG KPV OVII 6,0 /SPRITZEN- EINSATZ TYP II NW18 W/W/TR
BATCH / *Chargen-Nr*	H23015_22204693
PRODUCTION DATE / *Herstelldatum*	06/12/23
SHELF LIFE / *Verfalldatum*	09/01/2028
PLANT ADDRESS / *Adresse der Produktionsstätte*	WERK IV REMY & GEISER STRASSE 1 98553 SCHLEUSINGEN DE GERMANY
CUSTOMER / *Kunde*	Panaxia Pharmaceutical Industries
ORDER NUMBER / *Auftr.-Nr.*	20077278
CUSTOMER ORDER NUMBER / *Kunde Auftr.-Nr.*	PO23000265
QUANTITY DELIVERED (kpcs) / *Stückzahl (kpcs)*	64 KP

We declare that the goods referred to the lot indicated above, received with the supply indicated in the aforementioned delivery note and attached to this document, have been tested and resulted to be IN ACCORDANCE with the product technical specifications and Defect Evaluation List by Editio Cantor Verlag Aulendorf, in the respective valid version – please refer to tables related to the supplied items category in the following pages.
Sampling plan: ISO 2859-1; level II; normal inspection
The control method and quality level of the supply, unless different specifications agreed with the Customer, are those defined in our Quality System.
The above particulars do not release the customer from the obligation to carry out an inspection of the received goods.
Kindly not that we cannot guarantee the suitability of the used material.
In order to ensure that your packaging system works safely, we recommend you perform tests with the corresponding liquid.
According to its formulation, the materials used to manufacture the supplied item comply with the following provisions:

- Regulations applicable to articles intended for contact with food:
  - Reg. 10/2011 EU and following amendments
  - Reg. 1895/2005/EC; Reg. 1935/2004/EC; Reg. 2023/2006/EC
- REACH regulation 1907/2006/EC
- Reg. 1223/2009/EC and following amendments
- Reg.2023/2006/EC and following amendments
- Dir 94/62/EC: relative to the content of heavy metals
- Class I Medical Devices DoC: refer to product specification.

COMPONENT	COMPONENT DESCRIPTION
L1 1731M-AR240001	KINDERGESICHERTES EINZELTEIL KG ÜK NW18 W
L1 4509M-AR240001	KINDERGESICHERTES EINZELTEIL KG KSK OVII TYP V; VI; VII 6,0 N
L1 8805A-AR240001	DOSIERHILFE SPRITZEN-EINSATZ TYP II NW18 TR

MATERIAL	COMPONENT	MATERIAL DESCRIPTION
30147	1731M-AR240001	PURELL ACP 6541 A

B0658	1731M-AR240001	FARBKONZENTRAT WEISS REMAFIN-EP-WEISS PL00075542-ZT ähnlich RAL 9016 2%ig
B0658	4509M-AR240001	FARBKONZENTRAT WEISS REMAFIN-EP-WEISS PL00075542-ZT ähnlich RAL 9016 2%ig
B0147	4509M-AR240001	PURELL ACP 6541 A
B0143	8805A-AR240001	PURELL PE1840H NATUR

Plant Quality Manager/ Qualitätsmanager *für den Produktionsstandort* Benny Mueller

PRÜFZERTIFIKAT NACH FEHLERBEWERTUNGSLISTE (EDITIO CANTOR VERLAG) 18, 19, 20, 22, 34 aktuelle Ausgabe
Test Certificate acc. to Defect Evaluation List (Editio Cantor Verlag) Vol. 18, 19, 20, 22, 34 in current edition

Angaben zur Lagerung: Es bestehen keine besonderen Anforderungen an Temperatur und Luftfeuchtigkeit. Jedoch sind häufige, große Temperaturschwankungen zu vermeiden damit sich kein Kondenswasser bildet. Ferner sollte die Einwirkung von Temperaturen über 45°C vermieden werden um Verformungen auszuschließen.
Storage conditions: There are no special requirements to temperature or humidity. However, high fluctuations in temperature have to be avoided, so that no condensation could be caused. Furthermore, a temperature above 45°C should be avoided, to prevent deformation.

Fehler-Nr. Attr.-no.	Fehler/Einzelmerkmal Defect/Individual characteristics	AQL	Entscheidung Result
	Anlieferung, Kennzeichnung, Verpackung / Delivery, labelling, packing		
	Die Fehlermerkmale beziehen sich hier nicht auf das Packmittel selbst, sondern auf Paletten und Packeinheiten (Gebinde).Für die Prüfung dieser Fehlermerkmale ist kein Stichprobenverfahren anwendbar. Die Vergabe bezüglich dieser Merkmale ist eine fehlerfreie Lieferung. Fehlerklasse 1 bedeutet in diesem Zusammenhang, dass das Packmittel in der vorliegenden Anlieferform nicht einsetzbar ist. Lässt sich die Ware mit geringem Aufwand durch Nachbesserung in einen verwendbaren Zustand bringen, so ist dies durchzuführen. The defect characteristics refer not to the packaging material itself but to the pallets and packaging units (containers). No random sampling method is applicable for the testing of these defect characteristics. The requirement for these defect characteristics is a shipment without defects. In this context Defect Class 1 means that the packaging material is not utilizable in the form supplied. If the goods can be brought into a utilizable state at little expense by means of reworking this is to be performed.		
18.01.01 19.01.01 20.01.01 22.01.01	(1)(3)(4)(5)(6) Palette und/oder Außenverpackung entspricht nicht der Vorschrift, beschädigt, verschmutzt (Packmittelspezifikation) /pallet and/or outer packaging does not meet packaging specification, damaged,soiled	-	+
19.01.04 20.01.02 /03	(1)(3)(4)(5)(6) Packschema falsch / Packaging scheme incorrect	-	+
18.01.03/04 19.01.06 20.01.06 22.01.03/04	(1)(3)(4)(5)(6) Kennzeichnung der Palette / (1)(3)(4)(5)(6) Gebinde muss der Vorschrift entsprechen / Labelling of the Pallet / Container must comply with the specification	-	+
18.01.05/07 19.01.09/10 20.01.08 22.01.05/06	(1)(3)(4)(5)(6) Einzelverpackung (Sterilverpackung) beschädigt, verschmutzt, unvollständig / Individual packs (Sterile Packing), damaged, soiled, incomplete	-	+
20.01.09/10	(1)(3)(4)(5)(6) Lieferantenstichprobe / Begleitpapiere, Qualitätsdokumente, Prüfzertifikat falsch / fehlen / Suppliers random sample / Accompanying documents, quality documents, test certificate incorrect / missing	-	+
	Untermischung / Intermixing		
18.03.01 19.02.01/02 20.02.01 22.03.01	(1)(3)(4)(5)(6) Untermischung / Intermixing	-	+
	Ausgangsmaterial / Starting material		
1.1.1/2 18.02.01/02 19.03.05 22.02.01/02	(1)(3)(4)(5)(6) Das Material (EP Edition 10 - 3.1.3; 3.1.4) (EP Edition 10 - 3.1.5; 3.1.6) / Die Einfärbung muss der Vorschrift entsprechen / The material / The colour must comply with the specification	-	+
20.04.10	(3)(6) Zusammenhaftende bzw. klebrige Gummiteile / rubber parts adhering to one another or sticking	0,40	+
	Sauberkeit / Cleanlines		
4.4.1 18.04.01/05/06 20.07.02 22.04.01/05/06	(1)(3)(4)(5)(6) Verunreinigung-gelangen ins Füllgut / Contamination - gets into contents, (1)(3)(4) Grenzwerte für Partikel überschritten / Agreed limits for particles exceeded	-	+
04.04.08 22.04.01 '03	(1)(4)(5)(6) Fremdeinschlüsse-Aussehen stark beeinträchtigt, > 1mmØ oder Anhäufung (3) mehrere fest anhaftende Fremdkörper, Flecken ≥ 0,2mm2 / lose Partikel/ Foreign bodies enclosed appearance markedly impaired, > 1mm Ø / Brandstellen flächenförmig / Burn-marks >2mm diameter	0,10	+
18.04.02 22.04. '04	(1)(4)(6) Im Material eingeschlossene Fremdkörper / Brandstellen punktförmig 0,5- 2mm Ø / Foreign bodies incorporated in the material / Scorch dots 0,5- 2mm Ø	0,40	+
04.04.09 22.01.04	(5) Brandstellen / Scorched spots (1)(4)(5)(6) Fremdeinschlüsse-Aussehen wenig beeinträchtigt < 1mm Ø / Foreign bodies enclosed- appearance less impaired, < 1mm Ø, Lose Materialreste / Loose material residues	2,50	+
	Verarbeitungsfehler / Processing Errors		
5.5.5 22.05.07	(3) Nicht ausgeformte Gummiteile,Risse, Riefen, Kerben, Löcher, Dichtigkeit (Funktion) beeinträchtigt / Incompletely formed rubber parts,tears, grooves, notches, holes, seal and or function impaired / Formgrat, Stanzfehler anhaftetende Fellreste / Flash, punching errors (4)(5) Risse, Spalten, Löcher, Teile nicht voll ausgespritzt, Fließnaht bricht auf / Tears, clets, holes, partsincompletely injected, seam breaks open (4) Kanal verstopft keine Dosierung möglich / Duct blocked dossage impossible, Im Bereich des Abtropfrandes und der dichtenden Flächen geraut-Dichtigkeit nicht gegeben / Roughness in the area of the dropping rim and of the sealing areas-seal not possible	-	+

Fehler-Nr. Attr.-no.	Fehler/Einzelmerkmal Defect/Individual characteristics	AQL	Entscheidung Result
	Verarbeitungsfehler / Processing Errors		
5.5.1 22.05.06/03/09	(5) Starke Formnähte u./o Rückstände an den Anspritzpunkten / Marked mould joints and or residues at the injection points Stark verzogene Teile / Markedly warpeditems (4) Deformierung / Deformation (1)(4) Anspritzpunkt entspricht nicht (seitlich max 0,5mm, zentarl max. 0,7 mm) / Injection point does not comply (lateral max. 0,5mm, centeral max. 0,7mm) Überspritzungen, (4) Formgrate an Dichtstellen (Over-injection, flash at the sealing points	0,10	+
18.05.12 22.05.08/09	(1) Oberfläche, Kontur uneben / Surface, Shape uneven	0,40	+
19.03.13 22.05.12	(4)(5)(6) Falten, Kerben, Kratzer, Formgrat / Folds, notches, scratches, flash	2,50	+
	Abmessungen; Gravur; Druck / Dimensions; Engraved text; Printing		
9.9.1 22.06.01	(4) Kanal Ø a.T. / Duct diameter out of tolerance, Dosierung/Tropfgeschwindigkeit muss der Vorschrift (Prüfvorschrift nach Vereinbarung) entsprechen / Dosage/dropping speed must comply with the specification (testing procedure according or agreement, Verbindungsstege abgerissen-anzahlmäßig mehr als die Hälfte der Stege / Connecting strip torn off-numerically more than half of the studs, (3)(4) Dichtigkeit / test for leaks, Originalitäts-Sicherungsring fehlt / Tamper-proof ring missing	-	+
18.06.03.01 20.09.01 22.06.01.01	(1) Sonstige Maße, Winkel, Radien außer Toleranz / Other dimensions, angles, radii out of tolerance (3) Abmessungen a.T. / Dimensions out of tolerance (4) weitere Maße außer Toleranz / Other dimensions out of tolerance	0,10	+
18.07.01 19.18.05 22.07.01	(1)(4)(6) Gravur fehlt, falsch u./o. unvollständig. / Engraved text missing, incorrect and/or incomplete, Druck, Prägung fehlt, falsch u/o unvollständig / Overprinting,embossed text missing, incorrect and/or incomplete Gewinde fehlt oder ist nur mangelhaft ausgebildet / Thread missing or only inadequately formed (4)(6) Druckfarbe falsch / Printing color incorrect, Druckbild fehlt, falsch / Prinzting image missing or incorrect	-	+
07.07.01 18.07.07 19.18.06 22.07.01/03	(5)(6) Gravur für Dosierung unvollständig - Dosierung nicht möglich / Engraved marks for dosage incomplete - Dosage not possible, Abmessungen entsprechen nicht / Dimensions do not comply, Text fehlt, falsch oder nicht lesbar / text absent, incorrect or illegible, Dosierung a.T. / Dosage out of tolerance, (1)(4)(6) Farbe, Prägefolie-Haftung nicht ausreichend / Colour, embossed film-not resistant to abrasion	-	+
	Montage / Mounting		
22.08.13/15	(4)(6) Kindergesicherter Verschluss-Funktion nicht gewährleistet / Childproof closure-function not ensured, Außenteil gerissen / External part torn	-	+
18.08.01/03/04 22.08.05/17/18	(1)(4)(5)(6) Einzelteil fehlt / Individual parts missing, Teile durch Montage beschädigt / Parts demaged by mounting, Teile falsch montiert / Parts incorrect mounted, (4)(6) Pipette zu tief in Sauger eingesetzt / Pipette set too deep into the teat, Tropfeinsdatz durch Montage beschädigt / Dropper insert damaged by mounting	0,10	+
	Fertigungsfehler Pipetten / Manufacturing defects Pipettes		
19.08.01	(6) Abgeplatzte Stelle/n, Deformierung/en, oder Glassspitze/n am vorderen Teil (Kugel) / Chipped arera(s), defomation or glass spike/s on the tip	0,25	+

*** falls zutreffend die dazugehörige Fehlerbewertungsliste** * if applicable the relevant Defect Evaluation List

+:Passed - Non passed

(1) Kunststoff-Stopfen, Trockenkapseln und Aufsteckkappen / Plastic Stoppers, Desiccators and Caps • (3) Gummiteile / Rubber Parts
(4) Spritzgussteile aus Kunststoff: Verschlüsse; Dichteinlagen und Dosierhilfen (Tropfer etc.) / Injection-moulded Parts Made of Plastic: Closures
(5) Applikatoren und Messeinrichtungen aus Kunststoff / Applicators and Measuring Devices Made of Plastic (6) Pipetten Monturen/Glass Pipette Dropper

Hiermit bestätigen wir, dass die Qualität des oben bezeichneten Produktes nach den gültigen Prüfnormen (*Sterilität entsprechend ISO 11135 bzw. 11137 in der jeweiligen aktuellen Ausgabe) gemäß Spezifikation (Ausführungsvorschrift, technischer Zeichnung) sowie der jeweils gültigen Fehlerbewertungsliste hergestellt, verpackt, *sterilisiert und geprüft wurden und die dabei zulässigen Grenzwerte nicht überschritten wurden. Soweit für das obige Produkt abweichende Vereinbarungen zwischen Hersteller bzw. Lieferant und Verwender (Kunden) bestehen, werden diese zugrunde gelegt. We hereby confirm that the quality of the products described above has been produced, packed, *sterilized, nspected and testet in accordance with the valid inspection and testing standards (*Sterility conforming ISO 11135 or 11137 in its current version)according to the specification (documentet procedure, technical drawing) and the Defect Evaluation List an did not exceed the permissible limits. Where alternative aggreement for the above product exist between the costumer and the manufacturer and/or supplier, the relevant values have been based on these.
*falls zutreffend / *if applicable

Für Folgeschäden beim Kunden (unerwartete Unterbrechung an Abfüllanlage, Prüfaufwand, Rückruf usw.), wird keine Haftung übernommen solange die Vorgaben gemäß Fehlerbewertungsliste eingehalten sind. For secondary failures by the costumer (secondary failures bottling plant, additional tests, product recall etc.),to assume no liability as lang as the standard in accord with Defect Evaluation List are adhered to.

Vorstehende Angaben entbinden nicht von der Durchführung einer Wareneingangskontrolle
The above particulars do not release the customer from the of obligation to carry out an inspection of goods received

Hubert De Backer nv

Customer ...: PANAXIA PHARMACEUTICAL MALTA (OPERATIONS) LTI

F.a.o. .....: QUALITY DEPARTMENT

Temse, 2/04/2024

CERTIFICATE OF CONFORMITY

This delivery contains the following articles :

Article Number	Quantity	Description + Item customer	Your ref.
T2133	25000	CAP 560 PP 099 WHITE PK000005-MT	PO24000111 dd. 20/03/2024 Our ref./Batch no 24-0432/00

Approved by : Jimmy De Bergé
Dispatch department

We certify that the above components have been subject to in-process control and, if applicable, other testing. They comply with the agreed specification and were manufactured using the agreed materials, according a certified quality management system to ISO 9001:2015, EN ISO 13485:2016 and EN ISO 15378:2017.

Released by : Gianina Sarman
QA department

FRM-KD-118.02

This document is created electronically and is valid without signature.

23/337-MT

SGD S.A.
Simplified joint stock company with capital of 44 081 866 Euros - Nanterre Trade and Companies Register N°B552 012 585 - VAT I/D : FR 29 552 012 585
Head Office and Sales Departements : Tour Liberty - 17 place des Reflets - 92097 Paris La Défense Cédex - France. Phone:+33(0)1 40 90 36 00 - Fax:+33(0)1 40 90 36 01
Postal address : Tour Liberty - 17 place des Reflets - CS 30300 - 92097 Paris La Défense Cédex - France

CERTIFICATE OF QUALITY

The 09.11.2023

Customer PANAXIA PHARMACEUTICAL MALTA / 39810
BBG3000 ESTATE BIRZEBBUGA MT

Delivery adress PANAXIA PHARMACEUTICAL MALTA / 39810001
BBG3000 ESTATE BIRZEBBUGA MT

Customer's order	PO23000277	**from** 04.09.2023	
Customer's product code	PRT-GI000201-MT		
Delivery	81535153	**Quantity Delivered**	34.320 PCE
SGD Product Code	52490 04 001	TROPFFLASCHE 10 ML	
SGD Drawing N	68713G	type 3 AMBER GLASS	
Treatment	None		
Run Number	N 231232	**Manufacturing Date** 28.04.2023 **to**	09.05.2023
Quantity per Pallet	17.160	**Production Site** SUCY EN BRIE	France

We, SGD S.A., hereby certify that the above referred bottles have been tested and are in conformity with :

THE SPECIFICATIONS IN FORCE

TO THE CURRENT ISO 15378 VERSION

THE HYDROLYTIC RESISTANCE

- To the requirements of the European Pharmacopoeia in force
- To the requirements of the USP in force
- Hydrolytic Resistance testing - Grain - is done at least once per year.

ARSENIC

- To the requirements of the European Pharmacopoeia in force
- To the requirements of the USP in force
- Arsenic tests are carried out once per year by Furnace

SPECTRAL TRANSMISSION

- To the requirements of the European Pharmacopoeia in force
- To the requirements of the USP in force

SGD S.A.
Simplified joint stock company with capital of 44 051 566 Euros - Nanterre Trade and Companies Register N°B552 012 585 - VAT I/D : FR 29 552 012 585
Head Office and Sales Departements : Tour Liberty - 17 place des Reflets - 92097 Paris La Défense Cédex - France. Phone:+33(0)1 40 90 36 00 - Fax:+33(0)1 40 90 36 01
Postal address : Tour Liberty - 17 place des Reflets - CS 30300 - 92097 Paris La Défense Cédex - France

CERTIFICATE OF QUALITY

The 09.11.2023

Customer PANAXIA PHARMACEUTICAL MALTA / 39810
BBG3000 ESTATE BIRZEBBUGA MT

Delivery adress PANAXIA PHARMACEUTICAL MALTA / 39810001
BBG3000 ESTATE BIRZEBBUGA MT

Customer's order	PO23000277	**from**	04.09.2023
Customer's product code	PRT-GI000201-MT		
Delivery	81535153	**Quantity Delivered**	34.320 PCE
SGD Product Code	52490 04 001	TROPFFLASCHE 10 ML	
SGD Drawing N	68713G	type 3 AMBER GLASS	
Treatment	None		
Run Number	N 231232	**Manufacturing Date**	28.04.2023 **to** 09.05.2023
Quantity per Pallet	17.160	**Production Site**	SUCY EN BRIE France

Glass quality

	Unit	Specifications		Results			
		Min	Max	Min	Max	Ave	S-D
ARSENIC	ppm	N/A	0,100	0,003	0,003	0,003	0,000
Hydro-resist-powder/1g	ml	N/A	0,850	0,560	0,570	0,570	0,000
Hydrolytic resistance (HCl)	ml	N/A	8,100	7,600	7,820	7,710	0,110
Spectral transmission	%	N/A	10,000	1,630	1,630	1,630	0,000
Annealing	N/A	N/A	18,000	Conforms			

Glass measurements

	Unit	Specifications		Results			
		Min	Max	Min	Max	Ave	S-D
Body diameter	mm	25,000	25,800	25,300	25,470	25,400	0,041
Mini Internal bore	mm	9,500	N/A	11,170	11,830	11,484	0,149
Neck finish height 2	mm	10,800	11,200	10,860	11,140	10,984	0,061
Maxi External neck	mm	N/A	18,000	17,730	17,970	17,856	0,048
Minox thread diameter	mm	15,680	15,980	15,690	15,820	15,765	0,030
Opening diameter	mm	10,450	10,750	10,610	10,750	10,696	0,035
Total height	mm	57,400	58,600	57,880	58,250	58,094	0,081
Neck finish diameter	mm	17,700	18,000	17,700	17,800	17,740	0,025
Bead diameter	mm	19,800	20,200	19,900	20,040	19,985	0,026
Neck finish height	mm	13,500	13,900	13,520	13,710	13,610	0,042

SGD S.A.
Simplified joint stock company with capital of 44 981 866 Euros - Nanterre Trade and Companies Register N°B552 012 585 - VAT I/D : FR 29 552 012 585
Head Office and Sales Departements : Tour Liberty - 17 place des Reflets - 92097 Paris La Défense Cédex - France. Phone:+33(0)1 40 90 36 00 - Fax:+33(0)1 40 90 36 01
Postal address : Tour Liberty - 17 place des Reflets - CS 30300 - 92097 Paris La Défense Cédex - France

CERTIFICATE OF QUALITY

The 09.11.2023

Customer PANAXIA PHARMACEUTICAL MALTA / 39810
BBG3000 ESTATE BIRZEBBUGA MT

Delivery adress PANAXIA PHARMACEUTICAL MALTA / 39810001
BBG3000 ESTATE BIRZEBBUGA MT

Customer's order	PO23000277	**from** 04.09.2023	
Customer's product code	PRT-GI000201-MT		
Delivery	81535153	**Quantity Delivered**	34.320 PCE
SGD Product Code	52490 04 001	TROPFFLASCHE 10 ML	
SGD Drawing N	68713G	type 3 AMBER GLASS	
Treatment	None		
Run Number	N 231232	**Manufacturing Date** 28.04.2023 **to**	09.05.2023
Quantity per Pallet	17.160	**Production Site** SUCY EN BRIE	France

Glass characteristics

	Unit	Specifications		Results			
		Min	Max	Min	Max	Ave	S-D
Weight	g	N/A	N/A	24,500	25,500	25,000	0,247
Capacity	ml	13,000	15,000	13,500	14,100	13,826	0,140
Vertical load	kg/cm	200,000	N/A	400,000	400,000	400,000	0,000
Thermal shock	N/A	42,000	N/A	Conforms			

Quality Manager

Laurent MILLET

PZ-FBL Band/Vol. 18,19,20,22,34 aktuelle Ausgabe / current Ed.	Prüfzertifikat nach Fehlerbewertungsliste (Editio Cantor Verlag) Test Certificate acc. to Defect Evaluation List	Remy & Geiser GmbH Werk I / Plant I Remy & Geiser Str. 1 98553 Hinternah

Kunde: / customer: Panaxia Pharmaceuticals

Art.-Bez.: / article name: DOSIERVERSCHLUSS / dosage closure
DOSIERVERSCHLUSSRSV 5,0 OVII /SPRITZEN-EINSATZNW18 W/TR

Auftr.-Nr. / Order No.: 21124205
Ihre Auftr.-Nr.: / Your order no.: PO21001728
LS-Nr.: / Packing slip no.: 22244775
Stückzahl: / Pieces supplied: 30000

Ident.-Nr. / Article no.: 6615MA
Ihre Ident.-Nr.: / Your article no.: CM-2074
Chargen-Nr.: / Batch no.: 127870
Stichprobe: / sampling size: 50 (315) quant. (qual)

Herstelldatum: / date of manufacture: 02/2022
Verfallsdatum: / shelf life if sterile then: 02/2027 sterile02/2025
Ursprungsland: / Country of origin: Deutschland
Zchn-Nr.: / drawing no.: 03006608-01

Angaben zur Lagerung: Es bestehen keine besonderen Anforderungen an Temperatur und Luftfeuchtigkeit. Jedoch sind häufige, große Temperaturschwankungen zu vermeiden, damit sich kein Kondenswasser bildet. Ferner sollte die Einwirkung von Temperaturen über 45°C vermieden werden um Verformungen auszuschließen.
Storage conditions: There are no special requirements to temperature or humidity. However, high fluctuations in temperature have to be avoided, so that no condensation could be caused. Furthermore, a temperature above 45°C should be avoided, to prevent distortion.

Materialzusammensetzung: polymer used:

Einfärbung: colouring agents:

1. Einzelteil: / 1. component part:	RANDTROPFER-SCHRAUBKAPPERSK 5,0 OVII NW18 W Purell ACP6541A (PEHD)	HT-MAB PE 9071 weiss /white 2-2,5%
2. Einzelteil: / 2. component part:	DOSIERHILFESPRITZEN-EINSATZ NW18 TR Purell 1840H (PELD)	
3. Einzelteil: / 3. component part:	#NV #NV	#NV
4. Einzelteil: / 4. component part:	#NV #NV	#NV
5. Einzelteil: / 5. component part:	0	

Stichprobenumfang nach Fehlerbewertungsliste (Quantitative Prüfung) / Sampling inspection to defect Evaluation list (quantitative (tests)
Entscheidung: + entspricht / Decision: + accepted
Prüfvermerk: / insp. Remark: QK

Fehler-Nr. Attr.-no.	Fehler/Einzelmerkmal Defect/individual characteristics	AQL	max.Fehler Defects	Entscheidung Decision
	Anlieferung, Kennzeichnung, Verpackung / Delivery, labelling, packing			
	Die Fehlermerkmale beziehen sich hier nicht auf das Packmittel selbst, sondern auf Paletten und Packeinheiten (Gebinde).Für die Prüfung dieser Fehlermerkmale ist kein Stichprobenverfahren anwendbar. Die Vergabe bezüglich dieser Merkmale ist eine fehlerfreie Lieferung. Fehlerklasse 1 bedeutet in diesem Zusammenhang, dass das Packmittel in der vorliegenden Anlieferform nicht einsetzbar ist, Lässt sich die Ware mit geringem Aufwand durch Nachbesserung in einen verwendbaren Zustand bringen, so ist dies durchzuführen. The defect characteristics refer not to the packaging material itself but to the pallets and packaging units (containers). No random sampling method is applicable for the testing of these defect characteristics. The requirement for these defect characteristics is a shipment without defects. In this context Defect Class 1 means that the packaging material is not utilizable in the form supplied. If the goods can be brought into a utilizable state at little expense by means of reworking this is to be performed.			
1	❶❷❸❹Palette und/oder Außenverpackung entspricht nicht der Vorschrift, beschädigt, verschmutzt (Packmittelspezifikation) /pallet and/or outer packaging does not meet packaging specification, damaged,soiled	0,00	0	+
2/3	❷❺Packschema falsch / Packaging scheme incorrect	0,00	0	+
1/3/4/5	❶❷❸❹Kennzeichnung der Palette / ❶❷❸❹❺ Gebinde muss der Vorschrift entsprechen / Labeling of the Pallet / Container must comply with the specification	0,00	0	+
5/6/7	❶❷❸❹Einzelverpackung (Sterilverpackung) beschädigt, verschmutzt, unvollständig / Individual packs (Sterile Packing), damaged, soiled, incomplete	0,00	0	+
8/9	❷❸Lieferantenstichprobe / Begleitpapiere, Qualitätsdokumente, Prüfzertifikat falsch / fehlen / Suppliers random sample / Accompanying documents, quality documents, test certificate incorrect / missing	0,00	0	+
	Untermischung / Intermixing			
1	❶❷❸❹❺Untermischung / Intermixing	0,00	0	+
	Ausgangsmaterial / Starting material			
1/2	❶❷❺Das Material (EP Edition 9.4 - 3.1.3; 3.1.4) (EP Edition 9.5 - 3.1.5; 3.1.6) / Die Einfärbung muss der Vorschrift entsprechen / The material / The colour must comply with the specification	0,00	0	+
1/2/3/4/5	❷Grundglas, Wasserbeständigkeit der Innenoberfläche/gemäß Glasgrießmethode, Lichtdurchlässigkeit, Farbe entspricht nicht der Vorschrift / Base glass,Water resistant of internal surface /acc.glass grain method, Light transmission of base glass, Color of base glass does not meet specification	0,00	0	+
10	❺zusammenhaftende bzw. klebrige Gummiteile / rubber parts adhering to one another or sticking	0,40	0 (3)	+
	Sauberkeit / Cleanlines			
1/5/6/7	❶❹Verunreinigung-gelangen ins Füllgut / Contamination - gets into contents, ❶❷❸❹ Grenzwerte für Partikel überschritten / Agreed limits for particles exceeded	0,00	0	+
1/3/8	❶❷❸Fremdeinschlüsse-Aussehen stark beeinträchtigt, > 1mmØ oder Anhäufung ❸mehrere fest anhaftende Fremdkörper, Flecken ≥ 0,2mm2 / lose Partikel/ Foreign bodies enclosed appearance markedly impaired, > 1mm Ø / Brandstellen flächenförmig / Burn-marks >2mm diameter	0,10	0 (1)	+
2/4	❶❹ Im Material eingeschlossene Fremdkörper / Brandstellen punktförmig 0,5- 2mm Ø / Foreign bodies incorporated in the material / Scorch dots 0,5- 2mm Ø	0,40	0 (3)	+
1	❷❹Nicht entfernbare Verunreinigungen innen ≥ 0,3mm² / Non-removable contamination inside ≥ 0,3mm²	0,40	0 (3)	+
2/4	❶❹entfernbare Verunreinigungen innen ≥ 0,3mm², außen ≥ 0,5mm2 / Removable contamination inside ≥ 0,3mm², outside ≥ 0,5mm²	1,00	0	+
3/4/7/9/10	❹ Brandstellen / Scorched spots ❶❷❸Fremdeinschlüsse-Aussehen wenig beeinträchtigt < 1mm Ø / Foreign bodies enclosed- appearance less impaired, < 1mm Ø, Lose Materialreste / Loose material residues	2,50	3 (12)	+

Ident.-Nr. Article no.:	6615MA	Ihre Ident.-Nr.: Your article no.:	CM-2074	Chargen-Nr.: Batch no.:	127870	Stichprobe: sampling size:	50 (315) quant. (qual)
Verarbeitungsfehler / Processing Errors							
2/7/15/17	❶Nicht ausgeformte Gummiteile,Risse, Riefen, Kerben, Löcher, Dichtigkeit (Funktion) beeinträchtigt / Incompletely formed rubber parts,tears, grooves, notches, holes, seal and or function impaired / Formgrat, Stanzfehler anhaftetende Fellreste / Flash, punching errors ❹❺Risse, Spalten, Löcher, Teile nicht voll ausgespritzt, Fließnaht bricht auf / Tears, clefts, holes, partsincompletely injected, seam breaks open ❷Durchgehende Risse / Wall penetrating cracks ❸Kanal verstopft keine Dosierung möglich / Duct blocked dossage impossible, Im Bereich des Abtropfrandes und der dichtenden Flächen geraut-Dichtigkeit nicht gegeben / Roughness in the area of the dropping rim and of the sealing areas-seal not possible	0,00	0	+
1/3/4/9/13	❺Starke Formnähte u./o Rückstände an den Anspritzpunkten / Marked mould joints and or residues at the injection points Stark verzogene Teile / Markedly warpeditems ❸Deformierung / Deformation ❶❹ Anspritzpunkt entspricht nicht (seitlich max 0,5mm, zentarl max. 0,7mm) / Injection point does not comply (lateral max. 0,5mm, centeral max. 0,7mm) Überspritzungen, ❸Formgrate an Dichtstellen (Over-injection, flash at the sealing points	0,10	0 (1)	+
8/9/12/15/19/08.1	❷Anrisse / Incipient cracks Absplitterungen im Dichtungsbereich / Chipping in area of seal Blasen, Einschlüsse>1,0mm / Gas bubbles, inclusions > 1mm, Kühlspannung außer Toleranz / Cooling stress out of tolerance Abgeplatzte Stelle(n), Deformierung/en oder Glasspitze(n) am vorderen Teil (Kugel) / Clipped place(s), deformity(ies) or glass spike(s) on tip (ball) ❶ Oberfläche, Kontur uneben / Surface, Shape uneven	0,40	0 (3)	+
6/8/12/13	❷verformte Behältnisse / Deformed containers Kratzer (Breite ≥0,2mm, Länge ≥ 20mm) / Scratches (width ≥ 0,2mmand length ≥ 20mm ❹❺Falten, Kerben, Kratzer, Formgrat / Folds, notches, scratches, flash	2,50	3 (12)	+
Abmessungen; Gravur; Druck / Dimensions; Engraved text; Printing							
1	❸Kanal Ø a.T. / Duct diameter out of tolerance, Dosierung/Tropfgeschwindigkeit muss der Vorschrift (Prüfvorschrift nach Vereinbarung) entsprechen / Dosage/dropping speed must comply with the specification (testing procedure according or agreement, Verbindungsstege abgerissen- anzahlmäßig mehr als die Hälfte der Stege / Connecting strip torn off-numerically more than half of the studs, ❹❺❻ Dichtigkeit / test for	0,00	0	+
1/2/3/6	❷Scheibel Ø, Tropfloch Ø, Biegung außerhalb der Toleranz / Diameter of annular flange, dropper hole, bend out of the tolerance ❶ sonstige Maße, Winkel, Radien außer Toleranz / Other dimensions, angles, radii out of tolerance ❸ Abmessungen a.T. / Dimensions out of tolerance ❹weitere Maße außer Toleranz / Other dimensions out of tolerance, Originalitäts-Sicherungsring fehlt / Tamper-proof ring missing	0,10	0 (1)	+
1/3	❶❹ Gravur fehlt, falsch u./o. unvollständig. / Engraved text missing, incorrect and/or incomplete. Druck, Prägung fehlt, falsch u/o unvollständig / Overprinting,embossed text missing, incorrect and/or incomplete Gewinde fehlt oder ist nur mangelhaft ausgebildet / Thread missing or only inadequately formed ❷Druckfarbe falsch / Printing color incorrect, Druckbild fehlt, falsch / Prinzting image missing or incorrect	0,00	0	+
1/6/7	❺Gravur für Dosierung unvollständig - Dosierung nicht möglich / Engraved marks for dosage incomplete - Dosage not possible, Abmessungen entsprechen nicht / Dimensions do not comply, Text fehlt, falsch oder nicht lesbar / text absent, incorrect or illegible, Dosierung a.T. / Dosage out of tolerance, ❶❹ Farbe, Prägefolie-Haftung nicht ausreichend / Colour, embossed film-not resistant to abrasion	0,10	0 (1)	+
4	❷Druckfarbe haftet nicht / Printing does not adhere	0,40	0 (3)	+
Montage / Mounting							
13/15	❶Kindergesicherter Verschluss-Funktion nicht gewährleistet / Childproof closure-function not ensured, Außenteil gerissen / External part torn	0,00	0	+
1/2/4/5/9/17/19	❶❸❻ Einzelteil fehlt / Individual parts missing, Teile durch Montage beschädigt / Parts damaged by mounting, Teile falsch montiert / Parts incorrect mounted, ❸Pipette zu tief in Sauger eingesetzt / Pipette set too deep into the teat, Tropfeinsdatz durch Montage beschädigt / Dropper insert damaged by mounting	0,10	0 (1)	+

*** falls zutreffend die dazugehörige Fehlerbewertungsliste *** if applicable the relevant Defect Evaluation List (1) Skip-Lot verfahren; skip-batch Process

❶Kunststoff-Stopfen, Trockenkapseln und Aufsteckkappen / Plastic Stoppers, Desiccators and Caps ❷Behältnisse aus Röhrenglas / Containers Made of Tubular Glass ❸ Gummiteile / Rubber Parts ❹Spritzgussteile aus Kunststoff: Verschlüsse; Dichteinlagen und Dosierhilfen (Tropfer etc.) / Injection-moulded Parts Made of Plastic: Closures ❺Applikatoren und Messeinrichtungen aus Kunststoff / Applicators and Measuring Devices Made of Plastic

Hiermit bestätigen wir, dass die Qualität des oben bezeichneten Produktes nach den gültigen Prüfnormen (*Sterilität entsprechend ISO 11135 bzw. 11137 in der jeweiligen aktuellen Ausgabe) gemäß Spezifikation (Ausführungsvorschrift, technischer Zeichnung) sowie der jeweils gültigen Fehlerbewertungsliste hergestellt, verpackt, *sterilisiert und geprüft wurden und die dabei zulässigen Grenzwerte nicht überschritten wurden. Soweit für das obige Produkt abweichende Vereinbarungen zwischen Hersteller bzw. Lieferant und Verwender (Kunden) bestehen, werden diese zugrunde gelegt. We hereby confirm that the quality of the products described above has been produced, packed, *sterilized, inspected and testet in accordance with the valid inspection and testing standards (*Sterility conforming ISO 11135 or 11137 in its current version)according to the specification (documentet procedure, technical drawing) and the Defect Evaluation List an did not exceed the permissible limits. Where alternative aggreement for the above product exist between the costumer and the manufacturer and/or supplier, the relevant values have been based on these.

*falls zutreffend / if applicable

Vereinbarte Artikelspezifikationen beinhalten die Unbedenklichkeit der Materialien nach Verordnung (EU) Nr. 10/2011, 1935/2004, RL94/62/EG, 1907/2006, 1223/2009,deren Herstellung nach2023/2006 und deren aktuellen Ergänzungen. Gleichzeitig wird die Konformität nach ISO 13485(aktuelle Ausgabe) und RL 93/42/EWG (Verordnung 2017/745) bestätigt

Agreed article Specifications includes the compliance of the materials with EU-regulations 10/2011/EC, 1935/2004/EC, guideline 94/62/EC, 1907/2006/EC, 1223/2009/EC, whose manufacturing based on 2023/2006/EC and the current amendments. At the same time, conformity with ISO 13485 (current edition) and RL 93/42 / EEC (Regulation 2017/745) is confirmed.

Für Folgeschäden beim Kunden (unerwartete Unterbrechung an Abfüllanlage, Prüfaufwand, Rückruf usw.), wird keine Haftung übernommen solange die Vorgaben gemäß Fehlerbewertungsliste eingehalten sind. For secondary failures by the costumer (secondary failures bottling plant, additional tests, product recall etc.),to assume no liability as long as the standard in accord with Defect Evaluation List are adhered to.

Vorstehende Angaben entbinden nicht von der Durchführung einer Wareneingangskontrolle
The above particulars do not release the customer from the of obligation to carry out an inspection of goods received.

Datum: 21.02.2022 Date:

Freigabe: ja / yes release:

Prüfer: i.A.

ADDITIONAL BY QA

Signature

Date 10.03.2022