PANAXIA
Pharmaceutical Industries

Certificate of Conformance

Authorisation of Batch Release for sale in the EU

Product name, dose, dosage form and pack size:	Naxiva Panaxol THC 10mg/ml CBD 10 mg/ml
Client:	Neuraxpharm Arzneimittel GmbH
Market:	Germany
Batch number:	24/242-MT
Quantity	695 KITS
Manufacturing Date:	16/10/2024
Expiry date:	09/2026
Active Ingredient Concentration:	THC 1.04% (w/w) (10mg/ml) CBD 1.04% (w/w) (10mg/ml)
Plant strain/s:	Charlotte Angel & Master Kosh

Deviations noted during manufacture:

☑ No Critical/Major deviations

☐ Critical/Major deviations were reported and properly investigated and closed

The following document are attached-

- *Certificate of analysis*
- *Herbal substance COA*
  - *Herbal substance batch Number: 24/173-MT Herbal substance Strain: Charlotte Angel*
  - *Herbal substance batch Number: 24/168-MT Herbal substance Strain: Master Kosh*
- *Package COA*
  - *10ml amber glass bottles - batch number: 23/337-MT*
  - *10ml amber glass bottles cap- batch number: 24/007-MT*
  - *1ml sterile graduated syringes for patient dosing: batch number: 24/104-MT*
  - *syringe cap - batch number: 24/003-MT*
  - *30ml amber glass bottles - batch number: 24/043-MT, 24/198-MT*
  - *30ml amber glass bottles cap- batch number: 22/183-MT*

PANAXIA
Pharmaceutical Industries

I hereby certify that all the manufacturing stages of this batch have been carried out in full compliance with EU GMP and the technical agreement in force. The herbal substance used for the production of the batch had not been irradiated during the growing of the product process. The batch is released for sale by the undersigned Qualified Person in accordance with EC directive 2001/83.

Qualified Person: Steve Lovell 19 Dec 2024
Signature & Date Name

Panaxia Pharmaceutical Malta (Operations) LTD,
HHF001A, Ħal Far Industrial Estate, Birżebbuġa, BBG3000, Malta
Company Reg. No: C91890 Contact Number: +356 27781570

Reference Specification Legacy Number: F-SPC-001

Panaxia Malta Batch No:	PRT Number:	Expiry Date:
24/208-MT	WP-000059-MT	09/08/2026

m/12/24

1. Specifications:

Test	Test Method	Specifications	Result
Identification[3]			
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[3]			
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%	0.1%
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			
Aflatoxin B1	SOP QC-131-MT/ VA45110 *Ph. Eur. 2.8.18* ◊	≤ 2 µg/Kg	UQL
Total Aflatoxins (B1, B2, G1, G2)		≤ 4 µg/Kg	UQL
Ochratoxin A[4]	SOP QC-322-MT /VA45118 *Ph. Eur. 2.8.22* ◊	≤151 µg /kg	UQL
Microbiological Quality [1,3]			
TAMC	MW024-01*VA52090* *Complies to Ph. Eur. 2.6.12* ◊	≤ 10^4 CFU/mL	< 10 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 [5]			
Ethanol	QC-140-MT/VA12301 GC-HS-FID	≤ 5000 ppm	NA
Assay			
CBN	QC-181-MT *DAB* £	≤ 2.5% m/m	0.03%
CBD		0.99% - 1.09% m/m (95-105 % from label claim)	1.02%
Δ9-THC		0.99% - 1.09% m/m (95-105 % from label claim)	1.03%
Vitamin E	QC-149-MT / VA14060	≥ 0.4% m/m	0.5%

Reference Specification Legacy Number: F-SPC-001

Panaxia Malta Batch No:	PRT Number:	Expiry Date:
24/208-MT	WP-000059-MT	09/08/2026 04/12/24

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.
Ochratoxins UQL – Under quantification limit. The result of Ochratoxin A that is less than 0.5 µg/kg is reported UQL.
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 CBN that is less than 0.05% from the label amount of THC and CBD are reported URL (0.005%)
◊ 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. For the CZ batch the result needs to be also approved to the limit and tests in Appendix-1
4. No need to test for Czech Republic batch
5. Residual Solvent – To be performed every 20th batch.

Consecutive batch number:	***Pesticides and Heavy metals testing required on Finished product:***
3	☐ Yes; ☒ No, results reported from Inflorescence COA/s. Batch no./s used during manufacturing: 24/173-MT, 24/168-MT

2. Product description:

30 ml (28.8g) of standardized cannabis extract diluted in MCT oil and vitamin E, at concentrations of THC 1.04% m/m (10 mg/ml), CBD 1.04% m/m (10 mg/ml).

3. Packaging:

30 ml amber glass bottle (PK-000007-MT) with a non-child resistant tamer evident screw cap and plug insert with connector to a syringe (PK-000008-MT) .

4. Shelf life: 24 months

5. **Storage conditions:** Store in a cool, dry place, protected from light and at a temperature not exceeding 25°C.

☒ **PASS** ☐ **FAIL**		
Analysed by: Shani Bonan	**Signature:**	**Date:** December 3, 2024
Following the review of the manufacturer's COA and in-house testing, the batch concerned is considered meeting/not meeting Panaxia's Specifications and requirements, hence this batch is: ☒ **Approved/** ☐ **Rejected.**		
QC approved by: CHRIS DEGIRA	**Signature:**	**Date:** 04/12/2024

Reference Specification Legacy Number: F-SPC-001

Panaxia Malta Batch No:	PRT Number:	Expiry Date:
24/208-MT	WP-000059-MT	08/2026

REVISION HISTORY				
Date	**Name of corrector**	**Version no**	**Details of correction (including Chapter No)**	**Reason of correction**
19/03/2024	Shani Bonan	01	New Document	CCF-MT-2024-23
27/11/2024	Shani Bonan	02	1. Included Residual Solvent skip-lot testing 2. Adding the method's number of QSI 3. Update the shelf life to 244 month	1. CC-0000016 2. CC-0000022 3. Update

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	27-Nov-2024 15:17
Review	Chris Desira	Head of Quality Assurance	28-Nov-2024 09:32
Send for Approval	Chris Desira	Head of Quality Assurance	28-Nov-2024 09:33
Approve	Chris Desira	Head of Quality Assurance	28-Nov-2024 09:34
Approve	Irene Zanetti	Qualified Person	28-Nov-2024 09:35
Approve	Shani Bonan	QC Manager	28-Nov-2024 10:23
QA Approval	Chris Desira	Head of Quality Assurance	28-Nov-2024 10:27

* 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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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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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

SGD S.A.
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Postal address : Tour CB 16 - 17 place des Reflets - CS 30300 - 92097 Paris La Défense Cédex - France

CERTIFICATE OF QUALITY

The 23.05.2023

Customer PANAXIA PHARMACEUTICAL INDUSTRIES / 39371
71201 LOD IL

Delivery adress PANAXIA PHARMACEUTICAL INDUSTRIES / 39371001
. LOD IL

Customer's order	PO23000121	**from**	25.04.2023	
Customer's product code	CM-2048			
Delivery	81521342	**Quantity Delivered**		9.702 PCE
SGD Product Code	02543 07 020	TROPFFL. 30 ML		
SGD Drawing N 69676I	**Treatment**	None	type 3 AMBER GLASS	
Run Number	N 231206	**Manufacturing Date**	03.04.2023 **to**	11.04.2023
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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CERTIFICATE OF QUALITY

The 23.05.2023

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71201 LOD IL

Delivery adress PANAXIA PHARMACEUTICAL INDUSTRIES / 39371001
. LOD IL

Customer's order	PO23000121	**from**	25.04.2023		
Customer's product code	CM-2048				
Delivery	81521342	**Quantity Delivered**		9.702	PCE
SGD Product Code	02543 07 020	TROPFFL. 30 ML			
SGD Drawing N 69676I	**Treatment**	None	type 3 AMBER GLASS		
Run Number	N 231206	**Manufacturing Date**	03.04.2023 **to**	11.04.2023	
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		0,100	0,050	0,050	0,050	0,000
Hydro-resist-powder/1g	ml		0,850	0,590	0,590	0,590	0,000
Hydrolytic resistance (HCl)	ml		6,100	4,640	4,940	4,790	0,150
Spectral transmission	%		10,000	1,630	1,630	1,630	0,000
Annealing			18,000	Conforms			

Glass measurements

	Unit	Specifications		Results			
		Min	Max	Min	Max	Ave	S-D
Body diameter	mm	31,900	32,900	32,120	32,270	32,206	0,034
Mini Internal bore	mm	9,500		10,930	11,820	11,483	0,186
Minor thread diameter	mm	15,680	15,980	15,760	15,870	15,815	0,026
Neck finish height 2	mm	10,800	11,200	10,970	11,090	10,999	0,032
Maxi External neck	mm		18,000	17,710	17,960	17,830	0,055
Opening diameter	mm	10,450	10,750	10,570	10,740	10,660	0,049
Body diameter	mm	31,900	32,900				
Total height	mm	78,500	80,100	79,250	79,850	79,475	0,108
Neck finish diameter	mm	17,700	18,000	17,710	17,810	17,745	0,026
Bead diameter	mm	19,800	20,200	19,900	20,070	20,002	0,039
Neck finish height	mm	13,500	13,900	13,530	13,700	13,610	0,040

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The 23.05.2023

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71201 LOD IL

Delivery adress PANAXIA PHARMACEUTICAL INDUSTRIES / 39371001
. LOD IL

Customer's order	PO23000121	**from** 25.04.2023	
Customer's product code	CM-2048		
Delivery	81521342	**Quantity Delivered**	9.702 PCE
SGD Product Code	02543 07 020	TROPFFL. 30 ML	
SGD Drawing N 69676I	**Treatment**	None	type 3 AMBER GLASS
Run Number	N 231206	**Manufacturing Date**	03.04.2023 **to** 11.04.2023
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			40,600	42,000	41,208	0,331
Capacity	ml	34,300	36,700	34,900	35,900	35,420	0,223
Vertical load	kg/cm	200,000		400,000	400,000	400,000	0,000
Thermal shock		42,000		Conforms			

Quality Manager

Laurent MILLET

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.

Article number	Manufacturer	Item
5249004001	SGD Pharma	10mL. type 3 amber glass bottles

Manuf. Batch No:	Panaxia Batch No:	Manuf. Expiry Date:
N 231232	23/337-MT	09/05/2023

1.0 Specifications:

Test	Test Method*	Specifications		Results (average)
Specifications and Description:				
Glass Quality	Supplier COA	Arsenic	<0.100 ppm	0.003
		Hydro-resist-powder/1g	<0.850 mL	0.570
		Hydrolytic resistance (HCL)	<8.100 mL	7.710
		Spectral transmission	<10.000%	1.630
		Annealing	<18.000	Complies
Glass Measurements	Supplier COA	Minor thread diameter	15.680 - 15.980 mm	15.765
		Mini internal bore	>9.500 mm	11.484
		Neck finish height 2	10.800 – 11.200 mm	10.984
		Maxi external neck	<18.000 mm	17.856
		Opening diameter	10.450 – 10.750 mm	10.696
		Neck finish diameter	17.700 – 18.000 mm	17.740
		Bead diameter	19.800 – 20.200 mm	19.985
		Neck finish height	13.500 – 13.900 mm	13.610
Glass characteristics	Supplier COA	Capacity	13.000 – 15.000mL	13.826
		Vertical load	>200.000 Kg/cm	400,000
		Thermal shock	>42.200	Complies
Color	Supplier COA	Amber		Complies
Length (L)	Measure Length using Calibrated Ruler	58.60 – 57.40 mm		57.96
Body Diameter (D)	Measure Length using Calibrated Caliper	25.80 – 25.00 mm		25.435 *
Appearance (bottom)	Check if designated mark is present on bottom side	10 mL mark		Complies

Equipment/Instrument used:	*Equipment/Instrument ID:*
Calibrated Caliper	CAL-01-MT
Calibrated Ruler	RUL-01-MT

*DV 20/11/2023

AUTHORIZATION		
ISSUED BY:	QC APPROVED BY:	QA APPROVED BY:
INITIALS AND DATE: 30/09/2021	INITIALS AND DATE: 30-09-2021	INITIALS AND DATE: 2 OCT 2021

QA AUTHORISED COPY

ESOS V04.3 S

INITIALS: DATE: 20 NOV 2023

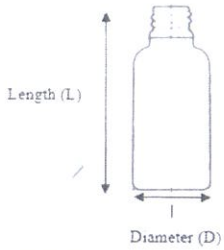

Figure 1: Physical Description

2.0 Packaging and Labeling

2.1 Each package must be labeled, by the manufacturer, with at least the following information:
- 2.1.1 Supplier name and address
- 2.1.2 Quantity per bag
- 2.1.3 Supplier article number and description
- 2.1.4 Supplier batch number
- 2.1.5 Packed on

2.2 Expiry date: 6 years from manufacturing date (Specified on SGD supplemented documentation)

3.0 Storage conditions:

3.1 Store in a cool dry location at a temperature lower than 30°C.

Sample Number	Length (mm)	Body Diameter (mm)
1	57.5	25.38
2	58.0	25.43
3	57.5	25.49
4	58.0	25.40
5	57.5	25.47
6	58.0	25.26
7	58.5	25.52
8	58.0	25.40
9	58.0	25.47
10	58.0	25.59
11	57.5	25.52
12	58.0	25.47
13	58.5	25.43
14	58.5	25.45

☑ PASS ☐ FAIL

Analysed by:	Signature:	Date:
Denise Vella	DV	20/11/2023

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:	Signature:	Date:
MARIA AGIUS		20-11-2023

DV 20/11/2023

AUTHORIZATION		
ISSUED BY:	QC APPROVED BY:	QA APPROVED BY:
INITIALS AND DATE: 30/09/2021	INITIALS AND DATE: 30-09-2021	INITIALS AND DATE: 2-10-2021

QA AUTHORISED COPY

INITIALS: DATE: 20 NOV 2023

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

Auftr.-Nr. Order No.:	22126354	**Ihre Auftr.-Nr.:** Your order no.:	PO22000312	**LS-Nr.:** Packing slip no.:	22248155	**Stückzahl:** Pieces supplied:	15000
Ident.-Nr. Article no.:	6615MA	**Ihre Ident.-Nr.:** Your article no.:	CM-2074	**Chargen-Nr.:** Batch no.:	111585	**Stichprobe:** sampling size:	50 (315) quant. (qual)
Herstelldatum: date of manufacture:	11/2020	**Verfallsdatum:** shelf life	11/2025	**Ursprungsland:** Deutschland Country of origin: Germany		**Zchn-Nr.:** drawing no.:	03006608-01
Sterilisationsdatum: date of sterilization:	entfällt						

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:	RANDTROPFER-SCHRAUBKAPPERSK 5,0 OVII NW18 W	
1. component part:	Purell ACP6541A (PEHD)	REMAFIN-EP-WEISS PL00075542-ZT
2. Einzelteil:	DOSIERHILFESPRITZEN-EINSATZ NW18 TR	
2. component part:	Purell 1840H (PELD)	
3. Einzelteil:	#NV	
3. component part:	#NV	#NV
4. Einzelteil:	#NV	
4. component part:	#NV	#NV
5. Einzelteil:	0	
5. component part:		

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

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	❶❷❹❺Palette 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 / ❶❷❹❺❻ Gebinde muss der Vorschrift entsprechen / Labelling 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	❶❹❺Das 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	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	❸zusammenhaftende bzw. klebrige Gummiteile / rubber parts adhering to one another or sticking	0,40	0 (3)	+
	Sauberkeit / Cleanliness			
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	❶❹❺Fremdeinschlüsse-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	❶❷entfernbare Verunreinigungen innen ≥ 0,3mm² außen ≥ 0,5mm2 / Removable contamination inside ≥ 0,3mm², outside ≥ 0,5mm²	1,00	0	+
3/4/7/9/10	❺ Brandstellen / Scorched spots ❶❹❺Fremdeinschlüsse-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.:	111585	Stichprobe: sampling size:	50 (315) quant. (qual)
Verarbeitungsfehler / Processing Errors							
2/7/15/ 17	❺Nicht 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, clefs, holes, partsincompletely injected, seam breaks open ❷Durchgehende Risse / Wall penetrating cracks ❹Kanal 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 ❹Deformierung / 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, ❺Formgrate 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) / Cipped 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 ❸❺Falten, Kerben, Kratzer, Formgrat / Folds, notches, scratches, flash	2,50	3 (12)	+
Abmessungen; Gravur; Druck / Dimensions; Engraved text; Printing							
1	❹Kanal 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, ❷❸❹ 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 ❶weitere 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 / Prinzing 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	❺Kindergesicherter Verschluss-Funktion nicht gewährleistet / Childproof closure-function not ensured, Außenteil gerissen / External part torn	0,00	0	+
1/2/4/5/ 9/17/19	❶❹❺ Einzelteil fehlt / Individual parts missing, Teile durch Montage beschädigt / Parts damaged by mounting, Teile falsch montiert / Parts incorrect mounted, ❹Pipette zu tief in Sauger eingesetzt / Pipette set too deep into the teat, Tropfeinsatz 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 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.

Datum: 31.08.2022 Date: Freigabe: release: ja / yes Prüfer: i.A.