

**Product Name: NAXIVA-PANAXOL CBD 250mg/g**  
**Reference Specification Legacy Number: F-COA-022-DE**

<b>Batch Details</b>			
<b>Batch number -Bulk oil</b>	FN 25002-00	<b>Manufacturing date</b>	07/2025
<b>Batch number - Finish product</b>	FP 25002-00 (FP 25002-00 DE)	<b>Expiry date</b>	07/2027

Test	Test Method	Specifications	Result
<b>Identification</b>			
TLC identification	SOP QC-179-MT/ VA1112 <i>DAB</i> <sup>£</sup>	Zonal pattern of test solution conforms to the zonal pattern of the reference solution	Complies
<b>Organoleptic properties</b>			
Appearance	SOP QC-136-MT Visual inspection <i>DAB</i> <sup>£</sup>	Homogenous greenish or yellow to brown liquid, no significant precipitate observed	Complies
<b>Heavy metals<sup>1,2</sup></b>			
Cadmium	SOP 77405 ICP-MS <i>Ph. Eur. 2.4.27</i> <sup>◊</sup>	≤ 1.0 ppm	0.05 ppm
Lead		≤ 5.0 ppm	0.1 ppm
Mercury		≤ 0.1 ppm	< 0.05 ppm
<b>Physico-chemicals</b>			
Relative density	SOP-183-MT / VA1044 <i>Ph. Eur. 2.2.5</i> <sup>◊</sup>	Indicative	0.97
Water content	SOP-175-MT/ VA25322 Karl Fisher <i>Ph. Eur. 2.5.12</i> <sup>◊</sup>	≤0.5%	< 0.2%
<b>Toxins- Mycotoxins</b>			
Aflatoxin B1	SOP QC-131-MT/ VA45110 <i>Ph. Eur. 2.8.18</i> <sup>◊</sup>	≤ 2 µg/Kg	< LOQ
Total Aflatoxins (B1, B2, G1, G2)		≤ 4 µg/Kg	< LOQ
<b>Microbiological Quality<sup>1</sup></b>			
TAMC	MW024-01/ VA52090, <i>Complies to Ph. Eur. 2.6.12</i> <sup>◊</sup>	≤ 10 <sup>4</sup> CFU/mL	< 100 CFU/ml
TYMC		≤ 10 <sup>2</sup> CFU/mL	< 10 CFU/ml
Bile-tolerant gram-negative bacteria	MW024-01/ VA52090, <i>Complies to Ph. Eur. 2.6.31</i> <sup>◊</sup>	< 10 <sup>2</sup> CFU/mL	< 10 CFU/ml
E.Coli		Absent in 1mL	Absent in 1 ml
Salmonella		Absent in 25 mL	Absent in 25 ml
<b>Residual solvent<sup>3</sup></b>			
Ethanol	QC-140-MT/ VA12301 GC-HS-FID	≤ 5000 ppm	NA
<b>Assay - Cannabinoids concentration (%w/w)</b>			
CBN	QC-181-MT <i>DAB</i> <sup>£</sup>	≤ 2.5% m/m	0.0%
CBD		23.75%-26.25%/m/m (95-105 % from label claim)	24.97%
Δ9-THC		1.43% - 1.58% m/m (95-105 % from label claim)	1.52%

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<b>Batch Details</b>			
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<b>Batch number - Finish product</b>	FP 25002-00 (FP 25002-00 DE)	<b>Expiry date</b>	07/2027

Vitamin E	QC-149-MT / VA14060	≥ 0.4% m/m	0.6%
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<b>Pesticide Residue</b> <sup>1,2</sup>			
Pesticides	SOP 15005, 15010 LC-MS/MS, GC-MS/MS, Headspace-GC/MS <i>Ph. Eur.2.8.13</i> <sup>3</sup>	<i>Complies with the limits indicated in Ph. Eur.2.8.13</i>	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 CBN and CBD that are less than 0.05% from the label amount of THC are reported URL (0.013% w/w)

<sup>3</sup> Current version of monograph

<sup>4</sup> DAB *Cannabis extractum normatum* monograph

1. Performed by approved outsource laboratory

2. Pesticides and Heavy metals - To be performed every 20<sup>th</sup> Batch. When skip lot testing is performed both results are reported from the Inflorescence COA.

3. Residual Solvent - To be performed every 20<sup>th</sup> batch.

<b>Consecutive batch no:</b>	<b>Pesticides and Heavy metals testing required on Finished product:</b>		
1	<input type="checkbox"/> Yes; <input checked="" type="checkbox"/> No, results reported from Inflorescence COA/s. Batch no./s used during manufacturing:	24/205-MT, 24/080-MT, 25/087-MT	

 **PASS  FAIL**

<b>QC Reviewed by:</b> Chris Desira	<b>Signature:</b> 	<b>Date:</b> July 30, 2025
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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.

<b>Approved by:</b> Shani Bonan	<b>Signature:</b> 	<b>Date:</b> July 30, 2025
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**REVISION HISTORY**

<b>Date</b>	<b>Name of corrector</b>	<b>Version no</b>	<b>Details of correction (including Chapter No)</b>	<b>Reason of correction</b>
13/02/2025	Shani Bonan	01	1. New Document 2. Adding the method's number of QSI 3. Adding Residual solvent - To be performed every 20 <sup>th</sup> Batch. 4. Remove Ochratoxin test	1. CCF-MT-2024-23 2. CC-0000022 3. CC-0000016 4. CC-0000033
17/06/2025	Shani Bonan	02	1. Updated Format of COA	1. CAPA-0000028

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)	Daniele Grasso	QA Specialist	20-Jun-2025 19:42
Send for Approval	Shani Bonan	QC Manager	22-Jun-2025 13:49
Review	Shani Bonan	QC Manager	22-Jun-2025 13:49
Approve	Shani Bonan	QC Manager	22-Jun-2025 13:49
Approve	Chris Desira	Head of Quality Assurance	23-Jun-2025 08:56
Approve	Irene Zanetti	Qualified Person	23-Jun-2025 09:07
QA Approval	Daniele Grasso	QA Specialist	23-Jun-2025 09:32

\* Dates are displayed according to the system time zone: (GMT+02:00) Central European Summer Time (Europe/Malta)



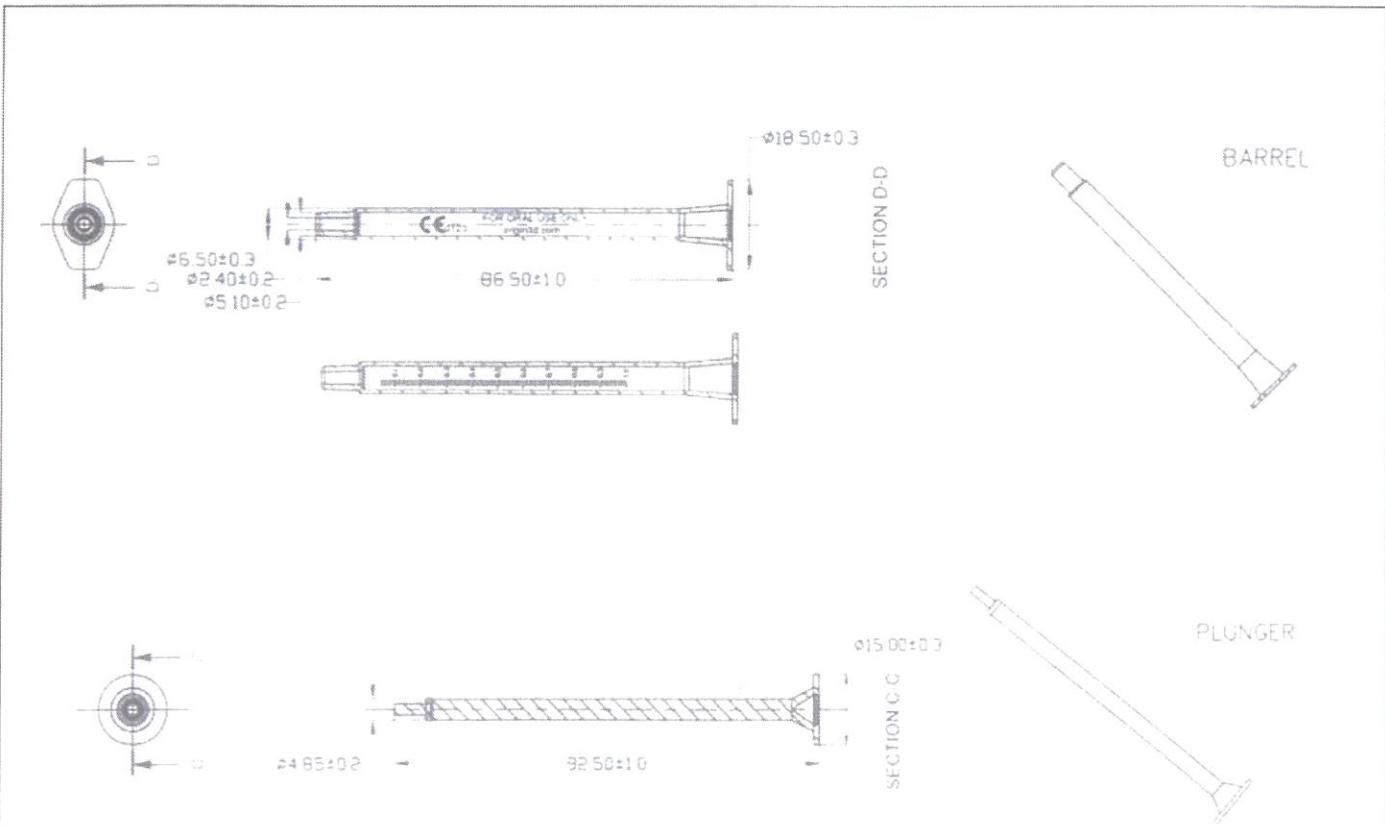
Document title	PRT Number	Document type	Document No.	Version
COA for 1mL Oral Dosage Syringe (Origin)	PK-000224-MT	COA	F-SPC-113-291-MT	02
Effective date: 12/06/2024			Page 1 of 2	

Product Code	Manufacturer/Supplier	Item
BRV240313/OS1W3-W	Bharat Rubber/Origin	1mL Oral Dosage Syringe

Manuf. Batch No:	Panaxia Batch No:	Manuf. Expiry Date:
BRV 240943	251092-MT	03-12-2027

### 1.0 Specifications:

Test	Test Method*	Barrel		Plunger	
		Specifications:	Results (average)	Specifications:	Results (average)
<b>Specifications and Description:</b>					
Material	Supplier COA	PP Purell RP375R	Complies	HDPE Purell ACP 6541A	Complies
Color	Supplier COA	Natural (Markings in black ink)	Complies	White (PL00075542)	Complies
Length (L)	Measure using Calibrated Ruler	85.5 – 87.5mm	85.7	91.5 – 93.5mm	92.7
External Diameter (D)	Measure using Calibrated Caliper	6.5±0.3mm	6.45	4.85mm±0.2mm	4.74



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

AUTHORIZATION		
ISSUED BY:	QC APPROVED BY:	QA APPROVED BY:
INITIALS AND DATE:	INITIALS AND DATE:	INITIALS AND DATE:
12 JUN 2024	12/06/2024	12/06/2024



Document title	PRT Number	Document type	Document No	Version
COA for 1mL Oral Dosage Syringe (Origin)	PK-000224-MT	COA	F-SPC-113-291-MT	02
Effective date: 12/06/2024			Page 2 of 2	

Sample Number	Length (mm)	External Diameter (mm)	Net Weight (g)
1	85.5	92.00	6.42
2	86.0	93.0	6.44
3	85.5	93.0	6.48
4	Barrel	Plunger	Barrel
5			Plunger
6			
7			
8			
9			
10			
Average	85.7	92.7	6.45
			4.74

## 2.0 Packaging and Labeling

### 2.1 Each box must be labeled, by the manufacturer, with at least the following information:

- 2.1.1 Supplier name and address
- 2.1.2 Supplier lot number (=order number)
- 2.1.3 Quantity
- 2.1.4 Supplier article number and description
- 2.1.5 For products marked with CE 0120:
  - 2.1.5.1 Shelf life
  - 2.1.5.2 The CE 0120 mark
  - 2.1.5.3 Symbol with storage instructions

### 2.2 Expiry date: 3 years from manufacturing date (Specified on material COA)

## 3.0 Storage conditions:

- 3.1 Store in a cool dry location.

<input checked="" type="checkbox"/> <b>PASS</b> <input type="checkbox"/> <b>FAIL</b>		
Analysed by: <i>Jennifer Riano Ortiz</i>	Signature: <i>JRO</i>	Date: <i>25-06-2025</i>
<i>Following the review of the manufacturer's COC and in-house testing, the batch concerned is considered meeting/not meeting Panaxia's Specifications and requirement, hence this batch is: <input checked="" type="checkbox"/> Approved/ <input type="checkbox"/> Rejected.</i>		
QC approved by: <i>Rosanna Demoul</i>	Signature: <i>RD</i>	Date: <i>26/06/2025</i>

## REVISION HISTORY

Date	Name of corrector	Version no	Details of correction (including Chapter No)	Reason of correction
20/05/2024	Chris Desira	01	New Document	CCF-MT2023-46
12/06/2024	Maria Agius	02	1. Updated product code and manufacturer/Supplier section to include reference to both manufacturer's and supplier's code 2. Updated colour of barrel and plunger to align with manufacturer's COA	1. Manufacturer COA does not include reference to supplier's product code. 2. Changes due to co-qualified grades of raw materials as communicated with Supplier.

## AUTHORIZATION

ISSUED BY: <i>S</i>	QC APPROVED BY: <i>R</i>	QA APPROVED BY: <i>W</i>
INITIALS AND DATE: <i>12 JUN 2024</i>	INITIALS AND DATE: <i>26/06/2024</i>	INITIALS AND DATE: <i>26/06/2024</i>



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

24/08-MT

## 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
ARSENIC	ppm	N/A	0,100	0,001	0,001	0,001
Hydro-resist-powder/1g	ml	N/A	0,850	0,520	0,520	0,000
Hydrolytic resistance (HCl)	ml	N/A	6,100	5,500	5,740	0,120
Spectral transmission	%	N/A	10,000	0,940	0,940	0,000
Annealing	N/A	N/A	18,000	Conforms		

### Glass measurements

	Unit	Specifications		Results		
		Min	Max	Min	Max	Ave
Body diameter	mm	31,900	32,900	32,120	32,310	32,224
Mini Internal bore	mm	9,500	N/A	11,000	11,730	11,376
Neck finish height 2	mm	10,800	11,200	10,970	11,090	11,015
Maxi External neck	mm	N/A	18,000	17,690	17,950	17,780
Minor thread diameter	mm	15,680	15,980	15,790	15,900	15,855
Opening diameter	mm	10,450	10,750	10,600	10,750	10,698
Total height	mm	78,500	80,100	79,170	79,570	79,417
Neck finish diameter	mm	17,700	18,000	17,730	17,890	17,810
Bead diameter	mm	19,800	20,200	19,840	20,050	19,989
Neck finish height	mm	13,500	13,900	13,500	13,620	13,570

.../..



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 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

<b>Delivery</b>	81563419	<b>Quantity Delivered</b>	19.404	PCE
<b>SGD Product Code</b>	02543 07 020	TROPFFL. 30 ML		
<b>SGD Drawing N</b>	69676I	Type III AMBER GLASS		
<b>Treatment</b>	None			
<b>Run Number</b>	N 241345	<b>Manufacturing Date</b> 14.06.2024	<b>to</b> 26.06.2024	
<b>Quantity per Pallet</b>	9.702	<b>Production Site</b> 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.

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## CERTIFICATE OF QUALITY

The 30.09.2024

**Customer****PANAXIA PHARMACEUTICAL MALTA / 39810**

BBG3000 ESTATE BIRZEBBUGA MT

**Delivery address****PANAXIA PHARMACEUTICAL MALTA / 39810001**

BBG3000 ESTATE BIRZEBBUGA MT

**Customer's order** PO24000326

from 27.08.2024

**Customer's product code** GI000201-MT

<b>Delivery</b>	81563419	<b>Quantity Delivered</b>	19.404	PCE
<b>SGD Product Code</b>	02543 07 020	TROPFFL, 30 ML		
<b>SGD Drawing N</b>	696761	Type III AMBER GLASS		
<b>Treatment</b>	None			
<b>Run Number</b>	N 241345	<b>Manufacturing Date</b>	14.06.2024	to 26.06.2024
<b>Quantity per Pallet</b>	9.702	<b>Production Site</b>	SUCY EN BRIE	France

**Glass characteristics**

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

**Quality Manager**

Aline BAILLET



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		
<b>Kunde: / customer:</b> Panaxia Pharmaceuticals				
<b>Art.-Bez.: / article name:</b> DOSIERVERSCHLUSS / dosage closure DOSIERVERSCHLUSSRSV 5,0 OVII /SPRITZEN-EINSATZNW18 W/TR				
<b>Auftr.-Nr. 21124205</b> Ihre Auftr.-Nr.: PO21001728 <b>LS-Nr.:</b> 22244775 <b>Stückzahl:</b> 30000 Order No.: Your order no.: <b>Packing slip no.:</b> <b>Pieces supplied:</b> <b>Ident.-Nr. 6615MA</b> Ihre Ident.-Nr.: CM-2074 <b>Chargen-Nr.:</b> 127870 <b>Stichprobe:</b> 50 (315) Article no.: Your article no.: <b>Batch no.:</b> <b>Sampling size:</b> quant. (qual) <b>Herstellidatum: 02/2022</b> <b>Verfallsdatum: 02/2027</b> Ursprungsland: Deutschland <b>Zchn.-Nr.:</b> 03006608-01 date of manufacture: shelf life if sterile then <b>sterile 02/2025</b> Country of origin: Germany <b>drawing no.:</b>				
<b>Angaben zur Lagerung:</b> 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 verhindert werden um Verformungen auszuschließen. <b>Storage conditions:</b> 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.				
<b>Materialzusammensetzung:</b> <b>Einfärbung:</b> polymer used: <b>colouring agents:</b> 1. Einzelteil: RANDTROPFER-SCHRAUBKAPPERSK 5,0 OVII NW18 W HT-MAB PE 9071 weiss /white 2-2,5% 1. component part: Purell ACP6541A (PEHD) 2. Einzelteil: DOSIERHILFESPRITZEN-EINSATZNW18 TR 2. component part: Purell 1840H (PELD) 3. Einzelteil: #NV 3. component part: #NV 4. Einzelteil: #NV 4. component part: #NV 5. Einzelteil: 0 5. component part:				
<b>Stichprobenumfang nach Fehlerbewertungsliste (Quantitative Prüfung)</b> Entscheidung: + entspricht Prüfvermerk: QK Sampling inspection to defect Evaluation list (quantitative tests) Decision: + accepted Insp. Remark:				
<b>Fehler-Nr.</b> Attr.-no.	<b>Fehler/Einzelmerkmal</b> Defect/Individual characteristics	<b>AQL</b>	<b>max.Fehler Defects</b>	<b>Entscheidung Decision</b>
<b>Anlieferung, Kennzeichnung, Verpackung / Delivery, labeling, packing</b>				
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 einsatzbar 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 utilisable in the form supplied. If the goods can be brought into a utilisable state at little expense by means of reworking this is to be performed.				
1	① ② ③ ④ Palette 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	① ② ③ Packschema falsch / Packaging scheme incorrect	0,00	0	+
1/3/4/5	① ② ③ ④ Kennzeichnung der Palette / ① ② ③ ④ Gebinde muss der Vorschrift entsprechen / Labeling of the Pallet / Container must comply with the specification	0,00	0	+
5/6/7	① ② ③ ④ Einzelverpackung (Sterilverpackung) beschädigt, verschmutzt, unvollständig / Individual packs (Sterile Packing), damaged, soiled, incomplete	0,00	0	+
8/9	② ③ Lieferantenstichprobe / Begleitpapiere, Qualitätsdokumente, Prüfzertifikat falsch / fehlen / Suppliers random sample / Accompanying documents, quality documents, test certificate incorrect / missing	0,00	0	+
1	<b>Untermischung / Intermixing</b>	0,00	0	+
1/2	<b>Ausgangsmaterial / Starting material</b> ① ② ③ Das 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	② Grundglas, Wasserbeständigkeit der Innenoberfläche/gemäß Glasgriffmethode, 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	② zusammenhaffende bzw. klebrige Gummitelle / rubber parts adhering to one another or sticking	0,40	0 (3)	+
<b>Sauberkeit / Cleanliness</b>				
1/5/6/7	① ② Verunreinigung-gelangen ins Füllgut / Contamination - gets into contents, ① ② ③ ④ Grenzwerte für Partikel Überschritten / Agreed limits for particles exceeded	0,00	0	+
1/3/8	① ② Fremdeinschlüsse-Aussehen stark beeinträchtigt, > 1mmØ oder Anhäufung ③ mehrere fest anhafternde Fremdkörper, Flecken ≥ 0,2mm² / loose Partikel/ Foreign bodies enclosed appearance markedly impaired, > 1mm Ø / Brandstellen flächenförmig / Burn-marks >2mm diameter	0,10	0 (1)	+
2/4	① ② 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	② ③ Nicht entfernbare Verunreinigungen innen ≥ 0,3mm² / Non-removable contamination inside ≥ 0,3mm²	0,40	0 (3)	+
2/4	① ② Entfernbare Verunreinigungen innen ≥ 0,3mm² außen ≥ 0,5mm² / Removable contamination inside ≥ 0,3mm², outside ≥ 0,5mm²	1,00	0	+
3/4/7/9/10	② Brandstellen / Scorched spots ① ② ③ Fremdeinschlüsse-Aussehen wenig beeinträchtigt < 1mm Ø / Foreign bodies enclosed- appearance less impaired, < 1mm Ø, Loose Materialreste / Loose material residues	2,50	3 (12)	+



Ident.-Nr. 6615MA Article no.:	Ihre Ident.-Nr.: CM-2074 Your article no.:	Chargen-Nr.: 127870 Batch no.:	Stichprobe: sampling size:	50 (315) quant. (qual)
Verarbeitungsfehler / Processing Errors				
27/15/17	④ Nicht ausgeformte Gummiteile, Risse, Riefen, Kerben, Löcher, Dichtigkeit (Funktion) beeinträchtigt / Incompletely formed rubber parts, tears, grooves, holes, seal and or function impaired / Formgrat, Stanzfehler anhaftetende Fellreste / Flash, puncting errors ④ ④ Risse, Spalten, Löcher. Teile nicht voll ausgespritzt, Fließnaht bricht auf / Tears, cts, holes, parts incompletely injected, seam breaks open ④ Durchgehende Risse / Wall paneling cracks ④ Kanal verstopft keine Dosierung möglich / Duct blocked dosage 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	④ Starke Formnähte u./o. Rückstände an den Anspritzpunkten / Marked mould joints and or residues at the injection points Stark verzogene Teile / Markedly warped items ④ Deformierung / Deformation ④ ④ Anspritzpunkt entspricht nicht (seitlich max 0,5mm, zentral max. 0,7mm) / Injection point does not comply (lateral max. 0,5mm, central max. 0,7mm) Überspritzungen, ④ Formgrate an Dichtstellen (Over-injection, flash at the sealing points	0,10	0 (1)	+
8/9/12/15/19/08.1	④ Anrisse / 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) ④ Oberfläche, Kontur uneben / Surface, Shape uneven	0,40	0 (3)	+
6/8/12/13	④ Verformte Behältnisse / Deformed containers Kratzer (Breite ≥ 0,2mm, Länge ≥ 20mm) / Scratches (width ≥ 0,2mm and length ≥ 20mm) ④ ④ Fallen, Kerben, Kratzer, Formgrat / Folds, notches, scratches, flash	2,50	3 (12)	+
Abmessungen; Gravur; Druck / Dimensions; Engraved text; Printing				
1	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, ④ ④ Dichtigkeit / test for	0,00	0	+
1/2/3/6	④ Scheibel Ø, Tropfloch Ø, Biegung außerhalb der Toleranz / Diameter of annular flange, dropper hole, bend out of the tolerance ④ sonstige Maße, Winkel, Radien außer Toleranz / Other dimensions, angles, radii out of tolerance ④ Abmessungen a.T. / Dimensions out of tolerance ④ weitere Maße außer Toleranz / Other dimensions out of tolerance, Originalitäts-Sicherungsring fehlt / Tamper-proof ring missing	0,10	0 (1)	+
1/3	④ ④ 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 Druckfarbe falsch / Printing color incorrect, Druckbild fehlt, falsch / Prinzing image missing or incorrect	0,00	0	+
1/6/7	④ 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, ④ ④ Farbe, Prägefolie-Haftung nicht ausreichend / Colour, embossed film-not resistant to abrasion	0,10	0 (1)	+
4	④ Druckfarbe hält nicht / Printing does not adhere	0,40	0 (3)	+
Montage / Mounting				
13/15	④ Kindergesicherter Verschluss-Funktion nicht gewährleistet / Childproof closure-function not ensured, Außenteil gerissen / External part torn	0,00	0	+
1/2/4/5/9/17/19	④ ④ Einzelteil fehlt / Individual parts missing, Teile durch Montage beschädigt / Parts damaged by mounting, Teile falsch montiert / Parts incorrect mounted, ④ Pipette zu tief in Sauger eingesetzt / Pipette set too deep into the seat, Tropfensatz 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				
④ Kunststoff-Stopfen, Trockenkapseln und Aufsteckkappen / Plastic Stoppers, Desiccators and Caps ④ Behältnisse aus Röhrenglas / Containers Made of Tubular Glass ④ Gummiteile / Rubber Parts ④ Spritzgussteile aus Kunststoff: Verschlüsse; Dichteinlagen und Doseierhilfen (Tropfer etc.) / Injection-moulded Parts Made of Plastic: Closures ④ Applikatoren und Messeinrichtungen aus Kunststoff / Applicators and Measuring Devices Made of Plastic				
<p>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 (Ausführungs vorschrift, 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 tested in accordance with the valid inspection and testing standards (*Sterility conforming ISO 11135 or 11137 in its current version) according to the specification (documented procedure, technical drawing) and the Defect Evaluation List an did not exceed the permissible limits. Where alternative agreement for the above product exist between the consumer and the manufacturer and/or supplier, the relevant values have been based on these.</p>				
*falls zutreffend / if applicable				
<p>Vereinbarte Artikelspezifikationen beinhalten die Unbedenklichkeit der Materialien nach Verordnung (EU) Nr. 10/2011, 1935/2004, RL94/62/EG, 1907/2006, 1223/2009, deren Herstellung nach 2023/2006 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, guidelines 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.</p>				
<p>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 customer (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.</p>				
<p>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.</p>				
Datum: 21.02.2022 Date:	Freigabe: ja / yes release:	Prüfer, I.A. 