

Goods Inwards inspection_bottle assy

Test Results Status

Step	Details	Result	Notes/Pass value
#1	Purpose of test: <ul style="list-style-type: none"> To ensure bottle assemblies have received appropriate level of Irradiation. To create electronic record of Irradiation Certificate. To visually inspect packaging. 		
#2	Record GRN number (goods received number) for shipment under inspection.	✓	Enter the value here : GRN number GR4962
#3	Record Lot number for shipment under inspection.	✓	Enter the value here : LOT 600716
#4	Perform visual inspection upon entire shipment. Confirm all packaging free from external damage. In the event of damage being discovered, raise defect report and record its number here.	✓	Enter the value here : DR If not applicable, goto #5
#5	Referring to QA procedure PRO-Sdo11 (Inspection Sampling Plan) perform detailed inspection in accordance with batch size.	✓	Done ? <input checked="" type="checkbox"/>
#6	Confirm Certificate of Irradiation supplied with bottle shipment. NB: In some cases, certificates may be sent in advance, these are located in Box File # BX0141. Use Lot number as search phrase within Box File data base to facilitate retrieval, as required.	✓	Done ? <input type="checkbox"/> Reference results at #3
#7	Record Certificate Number FR01512668134-1-1	✓	Enter the value here : Cert of Irradiation number
#8	Record Date Issued as printed upon Certificate of Irradiation. 24 May 2022	✓	Enter the value here : 24-5-22
#9	From Irradiation Data (printed upon certificate) record Minimum Calculated Dose. Confirm Minimum Calculated Dose not less than 25 kGy.	✓	25 kGy > 24.999 kGy
#10	If completing this test instruction on paper, attach copy of the Irradiation Certificate to this test instruction.	✓	Done ? <input checked="" type="checkbox"/> If not applicable, goto #11
#11	If completing this instruction electronically, photograph the first page of Certificate of Irradiation (Ensure photograph legible before attaching)		N/A If not applicable, goto #12
#12	If completing this instruction electronically, photograph the second page of Certificate of Irradiation (Ensure photograph legible before attaching)		N/A If not applicable, goto #13
#13	From Part Number Generator, print current revision of Bottle Assembly Label (# LA101713) Confirm all boxes within shipment are labelled with current issue of Bottle Assembly Label.	✓	Done ? <input checked="" type="checkbox"/>
#14	From Buyer or Production Director, ascertain and record date of manufacture for Bottle Assemblies within shipment.	✓	Enter the value here : 2022-04-28
#15	Confirm all boxes within shipment are marked with correct USE BY date. This must be 4 years from date of manufacture. (Refer to date of manufacture recorded in previous step as required)	✓	Done ? <input checked="" type="checkbox"/> 2026-04-28 Reference results at #13
#16	End of test.		

Approvals:

Signature & Date stamp

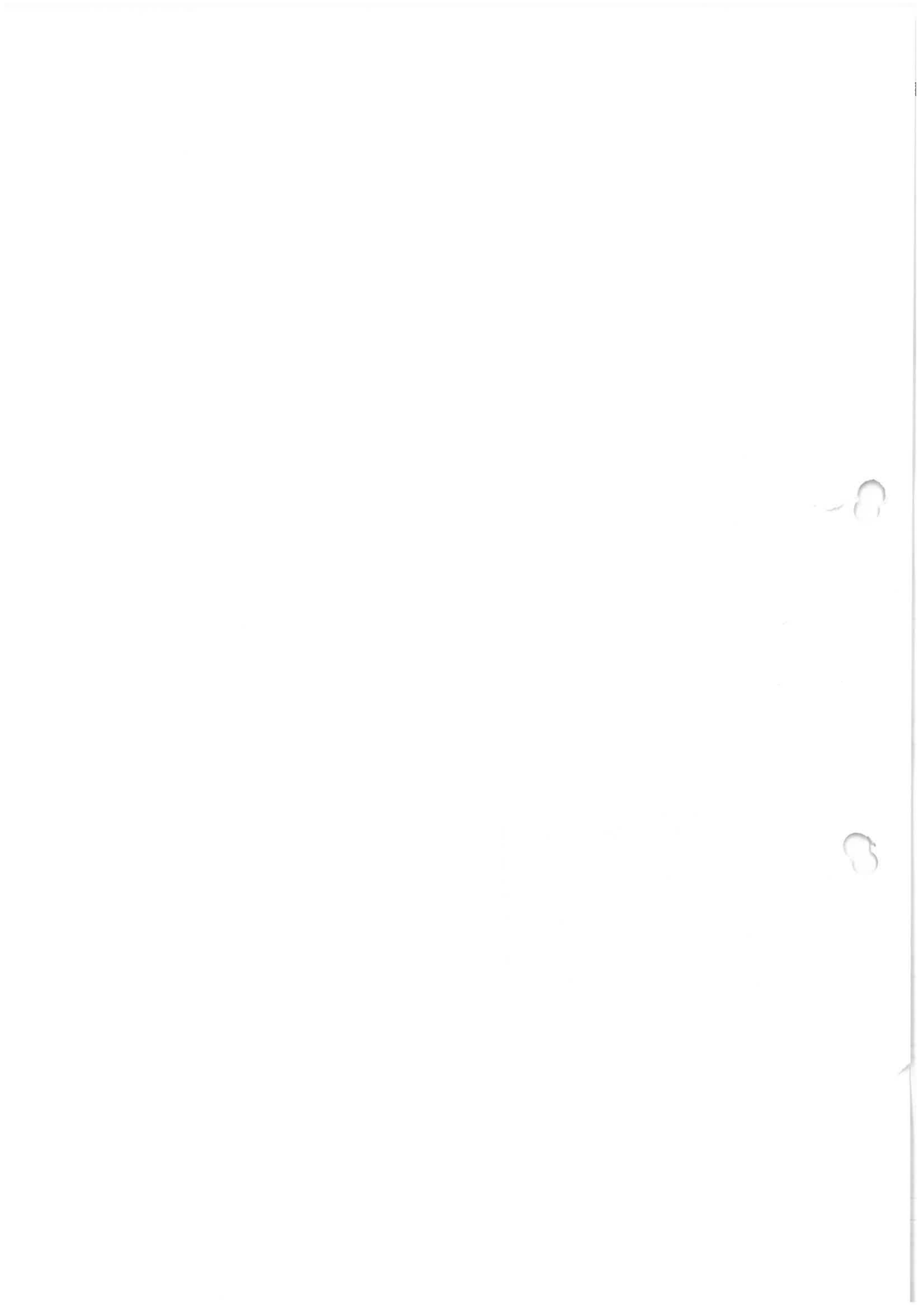
SEMBLER/TESTER

APPROVER (Test auditor)

Name of tester

Name of Approver







<http://www.steris-ast.com>

Certificate of Irradiation

Date Issued: 24-May-2022

FR01S12668134-1-1

This is to certify that Synergy Health Marseille, a STERIS Company has where appropriate delivered an irradiation process in accordance with the current certified standards:

EN ISO 11137-1 Sterilisation of Health Care Products
EN ISO 13485 Quality System - Medical Devices

PROMEPLA
Le Copori
9 avenue ALbert II
MONACO
98000
MONACO

Order Information

Account Number:	104501
Synergy Health Sales Part Reference:	1127465
Customer Reference Number:	473/PLANER PLC - 28/04/2022
Product Description:	496618P - PRODUITS CULTURE CELLULAIRE
Validation Reference:	S12029202
Quantity Received:	7
Customer Minimum Specification kGy:	25.0
Customer Maximum Specification kGy:	45.0
Customer Unit Lot/Batch Number:	G007116

Irradiation Data

Date and Time of Irradiation:	24-MAY-2022 04:59
Calculated Minimum Dose kGy:	28.5
Calculated Maximum Dose kGy:	42.3

CN101568-1	Qty:3,360 Each
Supp Ref:	
Bin:QS/BOTTLE	GRN:GR4962
	Purchase Order #PN2803
LOT:G007116	EXP:28/04/2026

Irradiation Release Authorised By Synergy Health Marseille SAS, a STERIS Company

Processing Site: M.I.N. 712 - Arnavaux, , Marseille Cedex 14, 13323 Phone No: +33 (0) 4 91 214 214

Registered Office: M.I.N. 712 - Arnavaux, 13323 Marseille Cedex 14, FRANCE
N° TVA: FR59 343 092 540

DE : PROMEPLA SAM

A : Synergy Health Marseille

Fax : + 33.4.91.214.218

COMMANDE & AVIS D'ENVOI

Nous vous informons que vous recevrez le :

29/04/2022

7 palettes / colis /

644 kg de :

PRODUITS POUR CULTURE
CELLULAIRE

N° Lot

Produit :

LOT G007116 QTE 3360

(réf. indiquées sur le certificat - 50 caractères maximum / espace incl.)

à traiter conformément à la Fiche de Spécification N°
(Ce numéro est impératif pour le traitement des produits.)

496618P

Date souhaitée de mise à disposition par Synergy Health pour enlèvement :

le :

AU PLUS TÔT

par :

BURGOS

[date souhaitée]

[transporteur]

Sauf avis contraire, ce délai de traitement est tacitement accepté.

Synergy Health se donne 24h ouvrables à réception de cette commande pour en modifier la date.

La référence de notre commande pour ces prestations est :
(réf. indiquées sur le certificat)

473/PLANER PLC

Autres instructions particulières :

RETOUR PROMEPLA FRANCE

Cette affaire est suivie par : Mme / Melle / Mr

S - BIANCHI

Tel :

377 97 98 42 32

Email :

sbi@promepla.com

Date :

28/04/22

Signature :

~~PROMEPLA S.A.M.~~
9, Avenue Albert II
Immeuble Le Copori
98000 MONACO
Phone number : (+377) 97 98 42 32
Mail : contact@promepla.com

Détail de la commande: 473

Référence	Ref client	Qté	Nb carton	Num lot	N° palette
CLIENT: PLANER PIC					
OOG00199SR148		0	48	G007116	R220020
OOG00199SR148		80	10	G007116	R220021
OOG00199SR148		480	48	G007116	R220022
OOG00199SR148		480	10	G007116	R220023
OOG00199SR148		480	10	G007116	R220024
OOG00199SR148		80	10	G007116	R220025
OOG00199SR148		400	10	G007116	R220026
		3360	146		



PROMEPLA

Signes, le 02/05/2022

stérilisation R (GAMMA) N°

473

Cycle de stérilisation du:

Lundi

Facturation à
PROMEPLA
9 Avenue Albert II
98000 MONACO

2 - 13323 Marseille Cedex 14

F
T 91.214.214 / Fax: 04.91.214.215

Spécification Stérilisation

Spécification de traitement selon N°496618P - OOG00195 R148

Descriptif des palettes: De la palette R220020 à la palette 220026

Observations:

Récapitulatif des palettes par client

Client:	Nb de palettes
PLANER PLC	7

Nombre de palettes: 7	Total HT	1604,82 €
Prix palette: 229,26 €	TVA 20%	320,96 €
	Total TTC	1 925,78 €

Nb de cartons

146

Quantité produits

3360

1	2	3	4
DRAWING No. LA101713			REPORT No. ER No. DATE ISSUE No.
A	THIRD ANGLE PROJECTION		EU REP & DATE OF MANUFACTURE ADDED ER10670 2021-04-01 6
			SHELF LIFE INCREASED FROM 29 MONTHS TO 4 YEARS ER10772 2021-09-23 7

**ETIQUETTE CARTON 2
BOX LABEL 2**

*Coller l'indicateur dans le cercle
Stick the indicator in the diameter*

PLANER

PLANER Ltd, 110 Windmill Road, Sunbury-on-Thames
Middlesex, TW16 7HD, United Kingdom
Tel : +44(0)1932 755000
E-mail : sales@planer.com Web : www.planer.com

DESCRIPTION : STERILIZED BOTTLE ASSEMBLY

REF	CN101568-1	Rx ONLY	CE 1639
CATALOGUE NUMBER			
STERILE R			
STERILIZED USING IRRADIATION	DO NOT REUSE	DO NOT USE IF THE PACKAGE IS DAMAGED	x48
	STORE IN A DARK PLACE AT ROOM TEMPERATURE		
DATE OF MANUFACTURE	2021-09-28	USE BY	2025-09-28

Do not use if package is damaged.
 Napočítajte, je-li balení poškozeno.
 Må ikke anvendes, hvis emballagen er beskadiget.
 Niet gebruiken indien de verpakking beschadigd is.
 Ei saa käyttää, jos pakkaus on vahingoittunut.
 Ne pas utiliser si l'emballage est endommagé.
 Inhalt bei beschädigter Verpackung nicht verwenden.

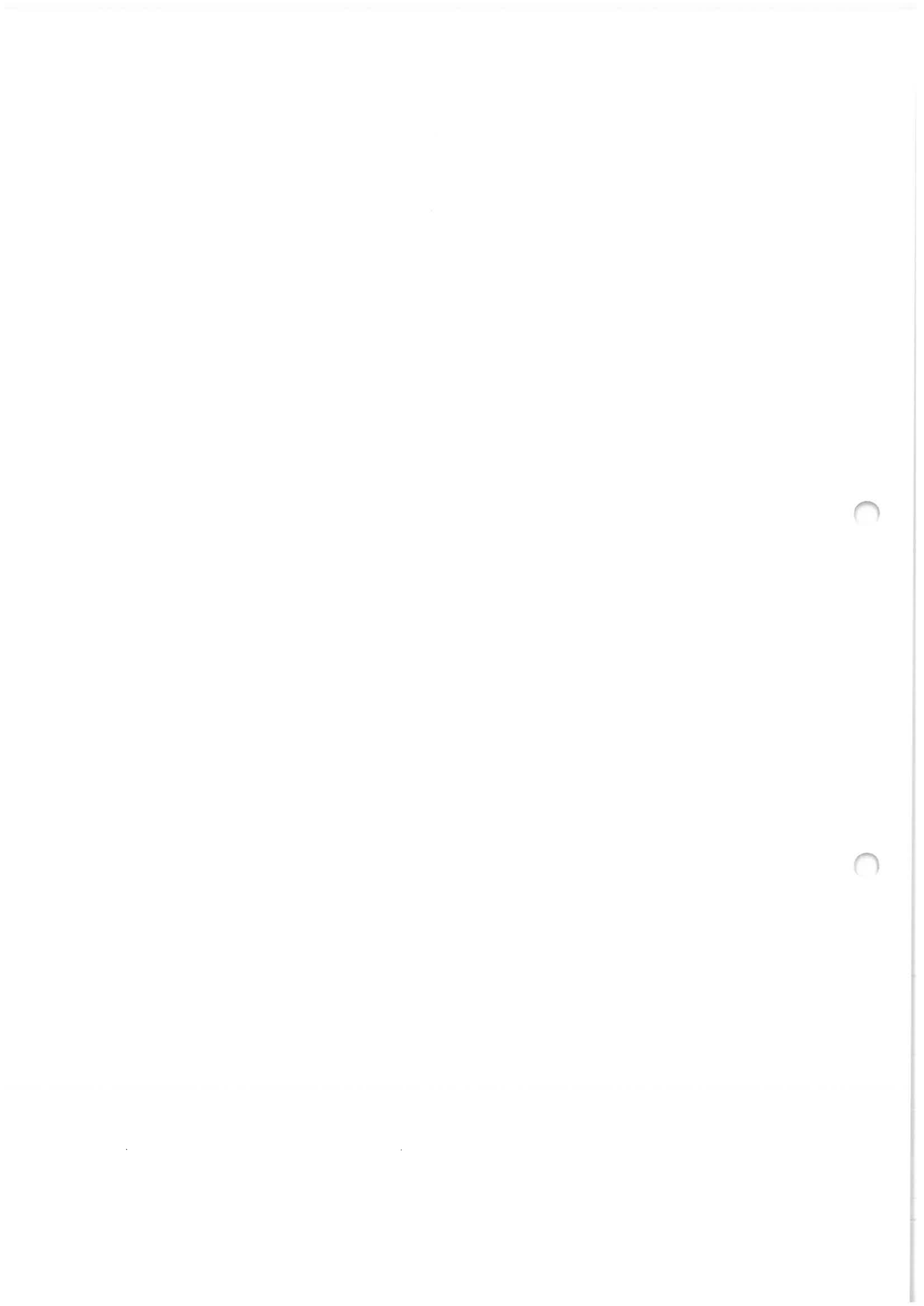
Μην το χρησιμοποιείτε εάν η συσκευασία έχει υποστεί ζημιά.
 Non utilizzare se la confezione è danneggiata.
 Nie stosować, jeżeli opakowanie zostało uszkodzone.
 Não utilizar se a embalagem estiver danificada.
 No utilizar si el envase está dañado.
 Får inte användas om förpackningen är skadad.
 Nepoužívat, ak je balenie poškodené.

EC REP Advena Ltd, Tower Business centre, 2nd Flr.,
 Tower Street, Swatar, BKR 4013 Malta

*Date de péremption
4 ans
Expiry date
4 years*

NOTE:
LABEL MATERIAL TO BE APPROVED BY PLANER BEFORE USE

DIMENSIONS: mm TOLERANCES DIMS TO 2 DP +/- 0.10mm DIMS TO 1 DP +/- 0.20mm DIMS TO 0 DP +/- 0.40mm HOLE DIA +0.15 -0.05mm ANGLE +/-0.5 DEG UNLESS OTHERWISE STATED	SCALE NTS MATERIAL SEE NOTE SPECIFICATION FINISH CLEAN	IMPORTANT NOTICE 1. COPYRIGHT <small>THIS DRAWING IS THE PROPERTY OF PLANER Ltd WHO OWN THE COPYRIGHT. THIS DRAWING IS SUPPLIED IN CONFIDENCE AND MAY NOT BE DISCLOSED FOR ANY REASON WHATSOEVER TO A THIRD PARTY WITHOUT THE WRITTEN CONSENT OF THE DIRECTORS OF THE COMPANY.</small> 2. INTERCHANGEABILITY <small>THIS DRAWING MAY ONLY BE ALTERED IF THE PART REMAINS INTERCHANGEABLE. IF NOT, A NEW DRAWING No. MUST BE USED.</small> 3. DRAWING ALTERATIONS <small>THIS DRAWING MAY ONLY BE ALTERED ON CAD.</small>	INSTRUCTIONS 1. WORK TO DIMENSIONS 2. DO NOT SCALE 3. REMOVE ALL SHARP EDGES AND CORNERS UNLESS OTHERWISE STATED 4. REPORT ANY OMISSION OR ERROR TO THE DESIGN DEPT 5. IF IN DOUBT ASK 6. MUST COMPLY WITH RoHS DIRECTIVE 2002/95/EC
DRAWN DATE SW 28.02.11	TITLE BOTTLE ASSY LABEL BOX No. 2		PARTS LIST No.
DRAWING SIZE A4 SOLIDWORKS	©2021	PLANER Limited SUNBURY-ON-THAMES MIDDLESEX TW16 7HD UK TEL: 01932 755000	DRAWING No. LA101713



PLANER

PLANER Ltd, 110 Windmill Road, Sunbury-on-Thames
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Tel : +44(0)1932 755000

E-mail : sales@planer.com

Web : www.planer.com

DESCRIPTION : STERILIZED BOTTLE ASSEMBLY

REF CN101568-1

Rx ONLY

CE 1639

LOT G007116

CATALOGUE NUMBER

BATCH CODE

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Ei saa käyttää, jos pakkaus on vahingoittunut.

Ne pas utiliser si l'emballage est endommagé.

Inhalt bei beschädigter Verpackung nicht verwenden.

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Tower Street, Swatar, BKR 4013 Malta



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