

### Goods inwards inspection\_BT37-02 bottle assembly

Test Results Status

Step	Details	Result	Notes/Pass value
	<b>Purpose of test:</b>		
#1	<ul style="list-style-type: none"> <li>To ensure bottle assemblies have received appropriate level of Irradiation.</li> <li>To create electronic record of Irradiation Certificate.</li> <li>To visually inspect packaging.</li> </ul>		
#2	Record GRN number (goods received number) for shipment under inspection.	✓	Enter the value here : GRN number <b>GR1858</b>
#3	Record Lot number for shipment under inspection.	✓	Enter the value here : LOT <b>G-006225</b>
#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 # BX0253. Use Lot number as search phrase within Box File data base to facilitate retrieval, as required.	✓	Done ? <input checked="" type="checkbox"/> Reference results at #3
#7	Record Certificate Number	✓	Enter the value here : Cert of Irradiation number <b>FR01S12579238-1-1</b>
#8	Record Date Issued as printed upon Certificate of Irradiation.	✓	Enter the value here : <b>6-7-21</b>
#9	From Irradiation Data (printed upon certificate) record Minimum Calculated Dose. Confirm Minimum Calculated Dose not less than 25 kGy.	✓	<b>25</b> kGy > <b>24.999</b> 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 (# LA200231) Confirm all boxes within shipment are labeled with current issue of Bottle Assembly Label.	✓	Done ? <input checked="" type="checkbox"/> <b>2021-05-28</b>
#14	From Buyer or Production Director, ascertain and record date of manufacture for Bottle Assemblies within shipment.	✓	Enter the value here : <b>2021-05-28</b>
#15	Confirm all boxes within shipment are marked with correct USE BY date. This must be 2 years + 5 months from date of manufacture. (Refer to date of manufacture recorded in previous step as required)	✓	Done ? <input checked="" type="checkbox"/> Reference results at #13
#16	End of test.		

**Approvals:**

Signature & Date stamp *J Adams*

ASSEMBLER/TESTER: **JACK Adams**      APPROVER (Test auditor):

Name of tester: **JACK Adams**      Name of Approver:

**END OF TEST RESULTS**

**PLANER PLC**  
**30 JUL 2021**  
**PRODUCTION**  
 SIGNED:.....



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

## Certificate of Irradiation

Date Issued: 06-Jul-2021

FR01S12579238-1-1

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

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### Order Information

Account Number:	104501
Synergy Health Sales Part Reference:	1134451
Customer Reference Number:	425/PLANER - 16/06/2021
Product Description:	496633P - OOG00799SR148
Validation Reference:	S12538885
Quantity Received:	2
Customer Minimum Specification kGy:	25.0
Customer Maximum Specification kGy:	45.0
Customer Unit Lot/Batch Number:	G006225

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### Irradiation Data

Date and Time of Irradiation:	05-JUL-2021 13:51
Calculated Minimum Dose kGy:	27.0
Calculated Maximum Dose kGy:	40.4

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

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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

Détail de la commande: 425

Référence	Ref client	Quantité	Nb carton	Num lot	N° palette
<b>CLIENT: PLANER PLC</b>					
00G00799SR148		400	10	G006225	R210073
00G00799SR148		400	10	G006225	R210074
		800	20		

# PROMEPLA SAMI

9. Avenue Albert II  
98000 Monaco

TEL : 00 377 97 98 42 32  
FAX : 00 377 92 05 61 50

E-mail : [sales@promepia.com](mailto:sales@promepia.com)  
Site : [www.promepia.com](http://www.promepia.com)

Monaco le 12/07/21

## Packing List N° BL211629

**PLANER LTD**  
110 WINDMILL ROAD  
MIDDLESEX  
TW16 7HD SUNBURY-ON-THAMES  
ANGLETERRE (UK)

### Delivery address

**PLANER PLC**  
110 WINDMILL ROAD  
UNIT F, DOLPHIN IND ESTATE  
TW16 7HD SUNBURY-ON-THAMES  
ANGLETERRE (UK)

Your Ref : PN044745

Code : CPLANER

Shipment : MONACO LOGISTIQUE  
N° Tracking : 80cmx1m20x1m94

Number of Cases : 20  
Handling Unit : 2  
Total Weight : 196

Part N°	Y/ Part N°	Description	Batch N° Compl.	Batch N°	Qty	Still to deliver
OOG00799SR148	CN200115	BT37 MKII - BOTTLE ASSEMBLY CUSTOMS 9018390000/ EORI NUMBER: FR00 00 0905900010/ FRANCE ORIGIN		G006225	960	

### CERTIFICATE OF COMPLIANCE

Barring all circumstances beyond our control, we here by certify that all the above-mentioned products bearing a batch number are in conformity with the technical specifications and have not undergone any modifications what's ever with respect to raw materials, processing or technical characteristics and are in accordance with our NF EN ISO 13485 : 2016 Quality System.

### EXTRACT OF GENERAL TERMS OF SALES

All our goods travel at the address's own risks.

**PROMEPLA S.A.M.**  
9. Avenue Albert II  
Immeuble Le Coporif  
98000 MONACO  
Phone number : (+377) 97 98 42 32  
Mail : [contact@promepia.com](mailto:contact@promepia.com)

A	1	2	3	4
	DRAWING No. <b>LA200231</b>			REPORT No.
				ER No. <b>ER1005</b>
B				DATE <b>05-02-20</b>
				ISSUE No. <b>1</b>
C				EU REP & DATE OF MANUFACTURE ADDED TO LABEL
				ER10678 19-04-21 <b>2</b>

**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- SINGLE TUBE VERSION**

**REF** CN200115 **Rx ONLY** **CE** 1639 **LOT** A302010  
 CATALOGUE NUMBER DO NOT REUSE DO NOT USE IF THE PACKAGE IS DAMAGED BATCH CODE

**STERILE R** **2021-04-28**  
 STERILIZED USING IRRADIATION DATE OF MANUFACTURE

**2023-09-28**  
 USE BY

**29 months**  
 Expiry date

Do not use if package is damaged.  
 Ne pouzivate, je-li baleni poškodeno.  
 Må ikke anvendes, hvis emballagen er beskadiget.  
 Niet gebruiken indien de verpakking beschadigd is.  
 Ei saa käyttää, jos pakkaus on vahingollunut.  
 Ne saa utiliser si femballage est endommagé.  
 Inhalt bei beschädigter Verpackung nicht verwenden.

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

**NOTE:  
LABEL MATERIAL TO BE APPROVED BY PLANER BEFORE USE**

<b>DIMENSIONS: mm</b>		<b>SCALE</b> 1:1	<b>IMPORTANT NOTICE</b>	<b>INSTRUCTIONS</b>
<b>TOLERANCES</b> UNLESS OTHERWISE STATED <b>ISO 2768-fH</b>		<b>MATERIAL</b> SEE NOTE	1. COPYRIGHT  THIS DRAWING IS THE PROPERTY OF PLANER LIMITED 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.	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. FINISHED PART MUST COMPLY WITH RoHS DIRECTIVE AND ANY AMMENDMENTS APPLICABLE AT THE TIME OF MANUFACTURE. 7. ALL DIMENSIONS NOT SHOWN ON DRAWING TO BE OBTAINED FROM 3D MODEL OR DXF FILE STATED IN MAIN VIEW
DIMENSIONS APPLY AFTER PLATING OR COATING		<b>SPECIFICATION</b>		
<b>SURFACE FINISH</b> UNLESS OTHERWISE STATED 1.6	<b>BREAK ALL EDGES</b> UNLESS OTHERWISE STATED -0.2 +0.2 -0.1 -0	<b>FINISH</b> CLEAN	<b>DRAWING SIZE A4</b> SOLIDWORKS	<b>©2021</b>
<b>DRAWN</b> SW	<b>DATE</b> 05-02-20	<b>THIRD ANGLE PROJECTION</b> 	<b>TITLE</b> <b>BOTTLE ASSY-SINGLE TUBE VER- BOX No. 2</b>	
			<b>APPROVED BY:</b>	
			<b>PLANER</b> PRESERVE / PROTECT / NURTURE SUNBURY-ON-THAMES MIDDLESEX TW16 7HD UK TEL: 01932 755000 FAX: 01932 755001	
			<b>DRAWING No.</b>	<b>SHEET 1 OF 1</b>
			<b>LA200231</b>	

# PLANER

PLANER Ltd , 110 Windmill Road, Sunbury-on-Thames  
Middlesex, TW16 7HD, United Kingdom

Tel : +44(0)1932 755000

E-mail : [sales@planer.com](mailto:sales@planer.com)

Web : [www.planer.com](http://www.planer.com)

DESCRIPTION : STERILIZED BOTTLE ASSEMBLY - SINGLE TUBE VERSION

REF CN200115

RX ONLY

CE

1639

LOT G006225

CATALOGUE NUMBER

BATCH CODE

STERILE R

STERILIZED USING IRRADIATION DO NOT REUSE

DO NOT USE IF  
THE PACKAGE  
IS DAMAGED



DATE OF  
MANUFACTURE



2021-05-28



STORE IN A DARK PLACE AT ROOM TEMPERATURE



2023-10-28

Do not use if package is damaged.

Nepoužívejte, je-li balení poškozeno.

Må ikke anvendes, hvis emballagen er beskadiget.

Niet gebruiken indien de verpakking beschadigd is.

Et 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