

### Goods inwards Inspection\_bottle assy

Test Results Status

Step	Details	Result	Notes/Pass value
#1	<b>Purpose of test:</b> <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>GR1857</b>
#3	Record Lot number for shipment under inspection.	✓	Enter the value here : LOT <b>G005476</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 # BX0141. 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>FR01S12573821-1-1</b>
#8	Record Date Issued as printed upon Certificate of Irradiation.	✓	Enter the value here : <b>0-6-21</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 > 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 : <b>2021-4-28</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.		

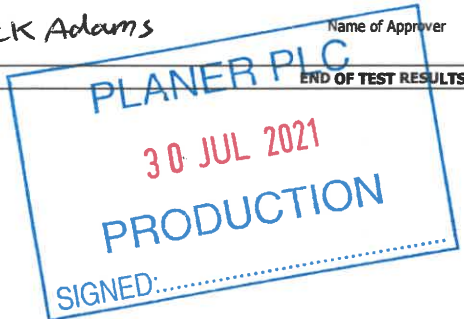
Approvals:  
Signature & Date stamp **J Adams**

ASSEMBLER/TESTER

APPROVER (Test auditor)

Name of tester **JACK Adams**

Name of Approver



END OF TEST RESULTS



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

## Certificate of Irradiation

Date Issued: 01-Jun-2021

FR01S12573821-1-1

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:	1127465
Customer Reference Number:	419/PLANER - 21/05/2021
Product Description:	496618P - PRODUITS CULTURE CELLULAIRE
Validation Reference:	S12029202
Quantity Received:	2
Customer Minimum Specification kGy:	25.0
Customer Maximum Specification kGy:	45.0
Customer Unit Lot/Batch Number:	G005476

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### Irradiation Data

Date and Time of Irradiation:	01-JUN-2021 06:54
Calculated Minimum Dose kGy:	28.7
Calculated Maximum Dose kGy:	40.2

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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: 419

Référence	Ref client	Quantité	Nb carton	Num lot	N° palette
<b>CLIENT: PLANER PLC</b>					
OOG00199SR148		480	10	G005476	R210061
OOG00199SR148		480	10	G005476	R210002
		960	20		

# PROMEPLA SAM

9, Avenue Albert II  
98000 Monaco

TEL: 00 377 97 98 42 32  
FAX: 00 377 92 05 61 50  
E-mail: sales@promepla.com  
Site: www.promepla.com

Monaco le 26/05/21

## Packing List N° BL211320

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: PN046125 Code: CPLANER

Shipment: MONACO LOGISTIQUE  
N° Tracking: 80cmx1m20x1m90  
Number of Cases: 20  
Handling Unit: 2  
Total Weight: 184

Part N°	Y/ Part N°	Description	Batch N° Compl.	Batch N°	Qty	Still to deliver
OOG00199SR148	CN101568-1	ASSEMBLED BOTTLE AND CAP - DISPOSABLE HUMIDIFICATION ASSY CUSTOMS 9018390000/ EORI NUMBER: FR00 00 0905900010/ EU ORIGINS FREIGHT		G005476	960	460
_FRAISPORT					1	

## PROMEPLA S.A.M.

9, Avenue Albert II  
Immeuble Le Copori  
98000 MONACO  
Phone number : ~~377~~ 97 98 42 32  
Mail : contact@promepla.com

### CERTIFICATE OF COMPLIANCE

Barring all circumstances beyond our control, we hereby certify that all the above-mentioned products bearing a batch number are in conformity with the technical specifications and have not undergone any modifications whatsoever with respect to raw materials, processing or technical characteristics and are in accordance with our NF EN ISO13485 : 2016 Quality System.

### EXTRACT OF GENERAL TERMS OF SALES

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

**DRAWING No.**  
**LA101713**

<b>REPORT No.</b>	<b>ER No.</b>	<b>DATE</b>	<b>ISSUE No.</b>
<b>Address prev Planer plc</b>	<b>ER10286</b>	<b>20.02.2020</b>	<b>5</b>
<b>EU REP &amp; DATE OF MANUFACTURE ADDED</b>	<b>ER10670</b>	<b>2021-04-01</b>	<b>6</b>

**THIRD ANGLE PROJECTION**

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

<b>REF</b> CN101568-1 <small>CATALOGUE NUMBER</small>	<b>Rx ONLY</b>	<b>CE</b> 1639	<b>LOT</b> E010203 <small>BATCH CODE</small>
<b>STERILE R</b> <small>STERILIZED USING IRRADIATION</small>	 <small>DO NOT REUSE</small>	 <small>DO NOT USE IF THE PACKAGE IS DAMAGED</small>	 <b>x48</b>
 <small>STORE IN A DARK PLACE AT ROOM TEMPERATURE</small>		 <b>2021-01-28</b> <small>DATE OF MANUFACTURE</small>	<b>2023-06-28</b> <small>USE BY</small>

Do not use if package is damaged.  
Nepoužívajte, 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.  
Nepoužívajte, ak je balenie poškodené.

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

*Date de péremption*  
*29 mois*  
*Expiry date*  
*29 months*

**NOTE:**

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

<b>DIMENSIONS: mm</b>	<b>SCALE NTS</b>	<b>IMPORTANT NOTICE</b>	<b>INSTRUCTIONS</b>
		<b>1. COPYRIGHT</b> <small>THIS DRAWING IS THE PROPERTY OF PLANER plc 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>	<b>1. WORK TO DIMENSIONS</b>
<b>TOLERANCES</b> 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  <small>UNLESS OTHERWISE STATED</small>	<b>MATERIAL SEE NOTE</b>	<b>2. INTERCHANGEABILITY</b> <small>THIS DRAWING MAY ONLY BE ALTERED IF THE PART REMAINS INTERCHANGEABLE. IF NOT, A NEW DRAWING No. MUST BE USED.</small>	<b>2. DO NOT SCALE</b>
	<b>SPECIFICATION</b>	<b>3. DRAWING ALTERATIONS</b> <small>THIS DRAWING MAY ONLY BE ALTERED ON CAD.</small>	<b>3. REMOVE ALL SHARP EDGES AND CORNERS UNLESS OTHERWISE STATED</b>
	<b>FINISH CLEAN</b>		<b>4. REPORT ANY OMISSION OR ERROR TO THE DESIGN DEPT</b>
<b>DRAWN SW</b>	<b>DATE 28.02.11</b>	<b>TITLE BOTTLE ASSY LABEL BOX No. 2</b>	<b>5. IF IN DOUBT ASK</b>
			<b>6. MUST COMPLY WITH RoHS DIRECTIVE 2002/95/EC</b>
<b>DRAWING SIZE A4 SOLIDWORKS</b>	<b>©2020</b>	<b>PLANER Limited SUNBURY-ON-THAMES MIDDLESEX TW16 7HD UK TEL: 01932 755000</b>	<b>PARTS LIST No.</b>
			<b>DRAWING No. LA101713</b>



# PLANER

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## DESCRIPTION : STERILIZED BOTTLE ASSEMBLY

**REF**

CN101568-1

Rx ONLY

CE

1639

**LOT**

G005476

CATALOGUE NUMBER

BATCH CODE

**STERILE**



STERILIZED USING IRRADIATION DO NOT REUSE

DO NOT USE IF  
THE PACKAGE  
IS DAMAGED



X48



2021-04-28

DATE OF

MANUFACTURE



STORE IN A DARK PLACE AT ROOM TEMPERATURE



2023-09-28

USE BY

Do not use if package is damaged.  
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Må ikke anvendes, hvis emballagen er beskadiget.  
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Ne pas utiliser si l'emballage est endommagé.

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Não utilizar se a embalagem estiver danificada.

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REP

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