



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

## Certificate of Irradiation

Date Issued: 10-Jan-2022

FR01S12636868-1-1

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:	1127163
Customer Reference Number:	461/PLANER PLC - 06/01/2022
Product Description:	496616P - ZAFSURBT04 WATER TRAY
Validation Reference:	S12124416
Quantity Received:	1
Customer Minimum Specification kGy:	25.0
Customer Maximum Specification kGy:	45.0
Customer Unit Lot/Batch Number:	N007402

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### Irradiation Data

Date and Time of Irradiation:	08-JAN-2022 17:22
Calculated Minimum Dose kGy:	26.0
Calculated Maximum Dose kGy:	34.2

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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

DE : PROMEPLA SAM

A : Synergy Health Marseille

Fax : + 33.4.91.214.218

**COMMANDE & AVIS D'ENVOI**

Nous vous informons que vous recevrez le :

07/01/2022

1 palettes / colis /

100

kg de :

Produits pour  
CULTURE  
CELLULAIRE

N° Lot

Produit :

LOT N007402 QTE 1920

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

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

496616P

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)

461/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 : 06/01/22

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: 461

Référence	Ref client	Quantité	Nb carton	Num lot	N° palette
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**CLIENT:** *PLANER*

OOG00499SR148		1920	20	N007402	R220001
		1920	20		

Dr 20143

Goods inwards inspection\_bottle-assy WaterTray CN103602

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
#3	Record Lot number for shipment under inspection.	✓	Enter the value here : LOT
#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
#8	Record Date Issued as printed upon Certificate of Irradiation.	✓	Enter the value here :
#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 (#LA103603) 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 :
#15	Confirm all boxes within shipment are marked with correct USE BY date. <del>This must be 4 years from</del> 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: **PLANER PLC**

ASSEMBLER/TESTER: *[Signature]* **08 FEB 2022**

Name of tester: **PRODUCTION** *Barbo*

APPROVER (Test auditor):

Name of Approver:

**SIGNED: \_\_\_\_\_ END OF TEST RESULTS**

1	2	3	4
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DRAWING No.  
**LA103603**

REPORT No.	ER No.	DATE	ISSUE No.
	ER10286	20.02.2020	3

A

**THIRD ANGLE PROJECTION**

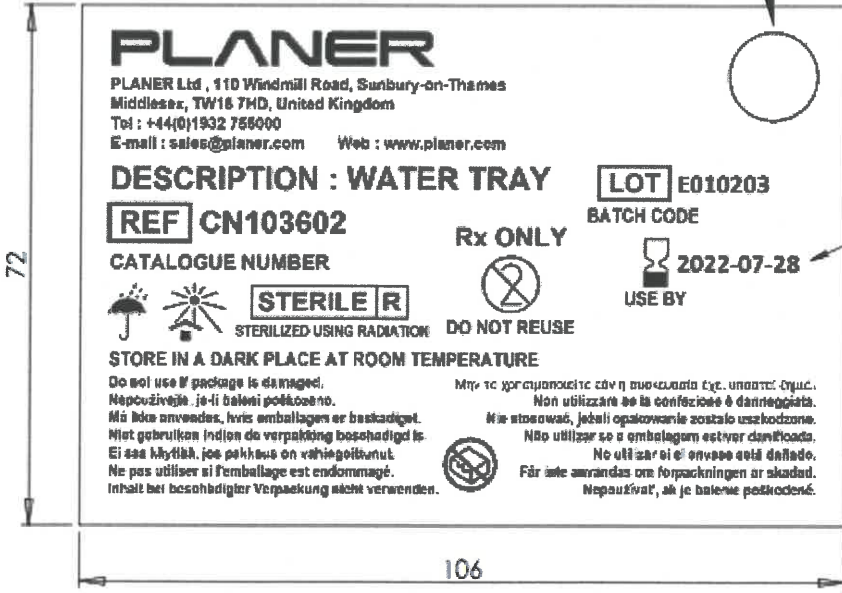
Address prev  
Planer plc

B

GAMMA INDICATOR LOCATION

**Etiquette produit**  
**Product Label**

C



**Attention / Warning**  
- Date de péremption de 29 mois  
- Expirate date of 29 month

D

**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>MATERIAL SEE NOTE</b>		<b>1. COPYRIGHT</b>		1. WORK TO DIMENSIONS.	
<b>TOLERANCES</b>		<b>SPECIFICATION</b>		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.		2. DO NOT SCALE.	
DIMS TO 2 DP	+/- 0.10mm			<b>2. INTERCHANGEABILITY</b>		3. REMOVE ALL SHARP EDGES AND CORNERS UNLESS OTHERWISE STATED.	
DIMS TO 1 DP	+/- 0.20mm			THIS DRAWING MAY ONLY BE ALTERED IF THE PART REMAINS INTERCHANGEABLE. IF NOT, A NEW DRAWING No. MUST BE USED.		4. REPORT ANY OMISSION OR ERROR TO THE DESIGN DEPT.	
DIMS TO 0 DP	+/- 0.40mm	<b>FINISH CLEAN</b>		<b>3. DRAWING ALTERATIONS</b>		5. IF IN DOUBT ASK.	
HOLE DIA	+0.15 -0.05mm			THIS DRAWING MAY ONLY BE ALTERED ON CAD.		6. FINISHED PART MUST COMPLY WITH RoHS DIRECTIVE AND ANY AMMENDMENTS APPLICABLE AT THE TIME OF MANUFACTURE.	
ANGLE	+/-0.5 DEG						
UNLESS OTHERWISE STATED							
<b>DRAWN SW</b>	<b>DATE 23-09-17</b>	<b>TITLE WATER TRAY LABEL</b>		<b>PARTS LIST No.</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>DRAWING No. LA103603</b>	